



HSE West and North West Cancer Clinical Trials Newsletter for Clinicians, Patients and Members of the Public

Cancer Clinical Trials

Currently Recruiting

June 2026

29 trials open across 5 cancer areas

30 TOTAL TRIALS	29 AT GALWAY UH	3 AT SLIGO UH
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**HSE West Northwest Cancer Clinical Trials
Open to Enrolling Participants**



Please find current cancer clinical trials open to participant enrolment in our HSE West and North West Health Region with contact details for clinician referral or self - referral.

If you are interested in running a clinical trial/ clinical research project within the region and/or need support in developing your protocol, please contact:

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12	Prof Maccon Keane
13	Prof Michael Kerin
14	Dr Lore Komanyane
15	Prof Janusz Krawczyk
16	Prof Joseph Martin
17	Dr Michael Martin
18	Dr Michael McCarthy
19	Dr Ronan McDermott
20	Dr Nicola Miller



Trial Summary

All recruiting trials at a glance. Detailed eligibility and contacts for each trial follow.

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BASKET TRIALS

6 trials in this section

1. DEPAC

FULL TITLE	A Randomised Controlled Trial of Deprescribing versus Standard of Care in Patients with Advanced Cancer
SITE	Galway University Hospital; Sligo University Hospital
PRINCIPAL INVESTIGATOR	Dr Julien O'Riordan; Dr Michael McCarthy; Prof Janusz Krawczyk; Dr Lars

✓ INCLUSION CRITERIA

- Aged 18 years or older
- Ability to read and understand English
- Diagnosis of advanced cancer
- Currently prescribed medications detailed in the OncPal deprescribing guidelines
- Suitable for de-prescribing as determined by the physician

✗ EXCLUSION CRITERIA

- Patients who do not consent to study participation
- Not currently taking any medication that can be deprescribed per OncPal International guidelines

STUDY COORDINATORS

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2. COOLVAS

FULL TITLE	Exploring the Feasibility and Impact of Cooling Mats on Vasomotor Symptoms in Patients Receiving Endocrine Treatment: A Pilot Study
SITE	Sligo University Hospital
PRINCIPAL INVESTIGATOR	Ms Breege Farrelly

✓ INCLUSION CRITERIA

- Adult aged 18 years or older
- Diagnosed with breast or prostate cancer
- Receiving endocrine therapy cancer treatment
- Experiencing vasomotor symptoms (e.g. hot flushes, night sweats)

✗ EXCLUSION CRITERIA

- Prior use of cooling mats for vasomotor symptoms
- Allergy to Polyvinyl chloride (PVC)
- Unable to co-operate with the study protocol
- Unable to give informed consent

STUDY COORDINATORS

Margaret Burke — Margaret1.burke@hse.ie

Moira Maxwell — Moira.Maxwell@hse.ie

3. SIMPLIFY-SABR-COMET

FULL TITLE	Single vs. Multiple fraction non-Inferiority trial of Stereotactic Ablative Radiotherapy for the Comprehensive treatment of Oligo-metastases/progression
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Dr Ronan McDermott

✓ INCLUSION CRITERIA

- 1–5 current oligometastatic or oligo-progressive lesions
- Histologically confirmed malignancy with metastatic disease detected on imaging
- Controlled primary tumour: at least 3 months since original tumour treated definitively, with no progression at primary site

✗ EXCLUSION CRITERIA

- Uncontrolled concurrent malignant cancer
- Lesion in femoral bone requiring surgical fixation
- Substantial overlap with a previously treated radiation volume
- Current malignant pleural effusion

STUDY COORDINATORS

Laura Nally — laura.nally@hse.ie

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4. E2-RADlatE (ReCare)

FULL TITLE	A prospective observational cohort on high-dose re-irradiation
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Professor Joseph Martin

✓ INCLUSION CRITERIA

- Pathologically confirmed cancer (local/locoregional recurrence, metastases or new primary) from: breast, NSCLC, SCLC, colorectal, prostate, endometrial, cervical, squamous H&N, glioma, or meningioma
- High-dose re-irradiation planned or ongoing
- Re-irradiation Type 1: new course with geometrical overlap with previous volume
- Re-irradiation Type 2: new course without geometrical overlap but with concerns of cumulative-dose toxicity

✗ EXCLUSION CRITERIA

- Life expectancy less than 3 months (per treating physician)
- Palliative non-therapeutic re-irradiation doses
- Missing information on previous radiotherapy

STUDY COORDINATORS

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5. CARES

FULL TITLE	A Phase 1/2 Trial of the Synthetic Cannabinoid ART27.13 in Patients with Cancer Anorexia and Weight Loss
SITE	Galway University Hospital; Sligo University Hospital
PRINCIPAL INVESTIGATOR	Prof Dympna Waldron; Dr Michael Martin

✓ INCLUSION CRITERIA

- Cancer documented by histopathology or cytology
- Anorexia: self-reported decrease/lack of appetite or aversion to food
- Documented unintentional weight loss of >5% with continuous downward trend over 6 months (± 2 weeks)
- No anti-cancer therapy for 2 weeks before enrolment and not expected for ~12 weeks, OR stable dose of anti-cancer therapy from 2 weeks pre-enrolment for a further ~12 weeks

✗ EXCLUSION CRITERIA

- Primary brain tumour or symptomatic brain metastasis
- Oral mucositis or oral fungal infection causing anorexia or impairing taste
- Unable to swallow food and oral medications
- On, recently on (≤ 4 weeks) or expected to be on medications affecting anorexia or caloric intake; on strong CYP3A4 inhibitors/inducers
- History of illicit drug, alcohol, or other drug misuse within the last 24 months
- Current medicinal cannabinoid use
- Recent diagnosis of clinical depression starting medication within 4 weeks prior to enrolment

STUDY COORDINATORS

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BREAST CANCER TRIALS

6 trials in this section

6. DESTINY-Breast15

FULL TITLE	A Phase 3b, Multicentre, Global, Open-label Study of Trastuzumab Deruxtecan (T-DXd) in Subjects with Unresectable and/or Metastatic HER2-low or HER2 IHC 0 Breast Cancer
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof Maccon Keane

✓ INCLUSION CRITERIA

- Must agree to provide newly obtained or archival baseline biopsy from primary and/or metastatic lesion
- Pathologically documented breast cancer that is unresectable and/or metastatic; HR-negative or HR-positive; HER2 IHC 1+ or 2+/ISH- (HER2-low) or HER2 IHC 0; never previously HER2-positive; never previously treated with anti-HER2 therapy in the metastatic setting
- At least one and up to two prior lines of therapy in the metastatic setting
- At least one measurable lesion on CT or MRI (≥ 10 mm in longest diameter), or non-measurable bone-only disease assessable by imaging
- Brain metastases allowed if small (< 2 cm), untreated, asymptomatic, clinically stable, and not requiring urgent intervention

✗ EXCLUSION CRITERIA

- Prior topoisomerase I inhibitor including prior participation in a DSI/AstraZeneca ADC study
- Uncontrolled or significant cardiovascular disease
- QTc prolongation > 470 ms (females) or > 450 ms (males) on screening ECG average
- History of non-infectious ILD/pneumonitis requiring steroids; current ILD/pneumonitis; or suspected ILD that cannot be ruled out on imaging
- Spinal cord compression or clinically active CNS metastases requiring steroids or anticonvulsants

STUDY COORDINATORS

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Trials Team (phone) — 087 2431601

7. MK2870-012

FULL TITLE	A Phase 3, Randomised, Open-label Study of Adjuvant MK-2870 plus Pembrolizumab versus Treatment of Physician's Choice in Participants with TNBC who Did Not Achieve pCR After Neoadjuvant Therapy
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof Maccon Keane

✓ INCLUSION CRITERIA

- Centrally confirmed TNBC
- No evidence of locoregional or distant relapse
- Neoadjuvant treatment based on the KEYNOTE-522 regimen followed by surgery per NCCN guidelines for TNBC; completed at least 5 doses of neoadjuvant pembrolizumab and chemotherapy including at least one dose of an anthracycline
- Adequate excision and surgical removal of all clinically evident disease with adequate recovery from surgery

✗ EXCLUSION CRITERIA

- Known germline BRCA mutation
- Grade >2 peripheral neuropathy
- History of severe dry eye syndrome, severe Meibomian gland disease, blepharitis, or corneal disease that delays/prevents corneal healing
- Active IBD requiring immunosuppression, or previous history of IBD

STUDY COORDINATORS

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8. ATNEC

FULL TITLE	Phase III Open-label Randomised Multicentre Trial Comparing Standard Axillary Treatment (ALND or Axillary RT) with No Axillary Treatment Post-Surgery in Early-Stage (T1–3 N1 M0) Breast Cancer Patients
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof Aoife Lowery

✓ INCLUSION CRITERIA

- Female or male with cT1–3 N1 M0 breast cancer
- Biopsy-proven axillary nodal metastases at presentation
- Radiologically node-negative (ycN0) after neoadjuvant chemotherapy

✗ EXCLUSION CRITERIA

- Distant metastases (M1)
- Incomplete or no neoadjuvant chemotherapy
- Residual clinically or radiologically positive nodes (ycN+)

STUDY COORDINATORS

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9. Relationships After Cancer

FULL TITLE	Relationship Changes Impacting Couples Following Breast Cancer Diagnosis — a cross-cultural study
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Ms Yimeng Du; Prof Paul Garrett; Prof Aoife Lowery; Dr Sonya Chew

✓ INCLUSION CRITERIA

- Diagnosed with local or regional breast cancer (Stages 0–III)
- Married or living with their partners
- Normal mental state
- Fluent in English

✗ EXCLUSION CRITERIA

- Under 18 years of age
- Previous participant in biobank programme

STUDY COORDINATORS

Ms Yimeng Du — y.du8@universityofgalway.ie



10.ECONSENT

FULL TITLE	A Randomised Controlled Trial to Test the Efficacy of Electronic Informed Consent versus Paper Informed Consent as a Methodological Approach for Biobank Research in Patients with Cancer
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof Michael Kerin

✓ INCLUSION CRITERIA

- Adult aged over 18
- Diagnosis of cancer and consenting to participate in the Biobank programme
- Able to read and understand English or Irish
- Consents to partake in this study

✗ EXCLUSION CRITERIA

- Does not meet the inclusion criteria above

STUDY COORDINATORS

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GYNAECOLOGY TRIALS

1 trial in this section

11.CATALINA-2

FULL TITLE	A Phase 2 Study of TORL-1-23 in Women with Advanced Platinum-Resistant Epithelial Ovarian Cancer (including Primary Peritoneal and Fallopian Tube Cancers) Expressing Claudin 6
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Dr Michael McCarthy

✓ INCLUSION CRITERIA

- Histologically or cytologically confirmed advanced (unresectable) or metastatic high-grade serous ovarian, primary peritoneal, or fallopian tube cancer (high-grade endometrioid ovarian cancer also permitted)
- Tumour positive for CLDN6 expression per the CLDN6 reference laboratory assay
- Platinum-resistant disease: after only 1 line of platinum-based therapy, completed ≥ 4 cycles of platinum, achieved CR or PR, and progressed > 3 but ≤ 6 months after last platinum dose
- Received at least 1 but no more than 3 prior systemic lines of anticancer therapy, with single-agent therapy appropriate as the next line
- Prior bevacizumab for ovarian cancer per label (unless ineligible due to precautions/intolerance, which must be documented)
- ECOG 0–1
- Measurable disease per RECIST 1.1

✗ EXCLUSION CRITERIA

- Clear-cell, mucinous, sarcomatous (including carcinosarcoma), mixed histology, low-grade, borderline, or non-epithelial ovarian tumours
- Primary platinum-refractory disease (no response or progression within 3 months of last dose of first-line platinum)
- Progressive or symptomatic brain metastases; leptomeningeal disease
- Prior treatment with a CLDN6-targeting agent or an MMAE-containing ADC
- History of non-infectious pneumonitis/interstitial lung disease (ILD)
- Grade ≥ 2 peripheral neuropathy

STUDY COORDINATORS

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LUNG CANCER TRIALS

5 trials in this section

12.MIRATI (Adagrasib)

FULL TITLE	A Phase 2 Trial of Adagrasib Monotherapy and in Combination with Pembrolizumab, and Phase 3 Trial of Adagrasib with Pembrolizumab vs Pembrolizumab in Advanced NSCLC with KRAS G12C Mutation
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Dr Silvie Blazkova

✓ INCLUSION CRITERIA

- Histologically confirmed NSCLC (squamous or non-squamous) with KRAS G12C mutation and PD-L1 tumour proportion score $\geq 50\%$ (both via central testing)
- Measurable disease per RECIST 1.1
- ECOG 0–1
- No prior systemic therapy for advanced disease

✗ EXCLUSION CRITERIA

- Prior KRAS G12C inhibitor treatment
- Untreated or unstable CNS metastases
- Active autoimmune disease
- History of CVA, TIA, or MI within 6 months

STUDY COORDINATORS

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13. NeoCOAST-2

FULL TITLE	Phase II, Open-label, Multicentre, Randomised Study of Neoadjuvant and Adjuvant Treatment in Patients with Resectable, Early-stage (II–IIIB) NSCLC
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Dr Silvie Blazkova

✓ INCLUSION CRITERIA

- Newly diagnosed, previously untreated, histologically or cytologically documented NSCLC
- Complete surgical resection of primary NSCLC must be deemed achievable at screening
- T4 tumours eligible only if T4 classification is based solely on size (>7 cm)
- Documented PD-L1 expression status

✗ EXCLUSION CRITERIA

- Sensitising EGFR mutations or ALK translocations
- History of allogeneic organ transplantation
- Active or prior documented autoimmune or inflammatory disorders (including IBD)
- Uncontrolled CNS metastases

STUDY COORDINATORS

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14.STK-012

FULL TITLE	A Phase 1/2 Study to Evaluate STK-012 as a Single Agent and in Combination Therapy in Subjects with Front-line Advanced NSCLC
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Dr Silvie Blazkova

✓ INCLUSION CRITERIA

- Stage IV (M1a, M1b or M1c) or stage IIIB/IIIC non-squamous NSCLC not amenable to definitive treatment
- No known actionable genomic alterations in EGFR, ALK, ROS1 or other AGA for which local SoC is available as 1L therapy
- No prior systemic treatment for advanced NSCLC

✗ EXCLUSION CRITERIA

- Systemic anti-cancer therapy within 3 weeks of first dose
- Prior IL-2-based or IL-15-based cytokine therapy
- History of idiopathic pulmonary fibrosis or drug/radiation induced pneumonitis

STUDY COORDINATORS

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Trials Team: 087 2431601

15.RASolve

FULL TITLE	RASolve 301: Phase 3 Multicenter, Open Label, Randomized Study of RMC-6236 versus Docetaxel in Patients with Previously Treated Locally Advanced or Metastatic RAS[MUT] NSCLC
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Dr Silvie Blazkova

✓ INCLUSION CRITERIA

- Pathologically confirmed locally advanced or metastatic NSCLC, not amenable to curative surgery or radiotherapy
- 1 or 2 prior lines of therapy including anti-PD-1/PD-L1 agent and platinum-based chemotherapy
- RAS mutation (KRAS, NRAS, or HRAS at codons 12, 13, or 61); G12C cohort closed
- ECOG PS 0 or 1

✗ EXCLUSION CRITERIA

- Prior RAS-directed therapy
- Other targetable driver mutations (EGFR, BRAF, ALK, ROS-1, TRK fusion) with available approved therapy
- Untreated CNS metastases or leptomeningeal disease

STUDY COORDINATORS

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Trials Team: 087 2431601

Genitourinary (GU)

16.Descalate

FULL TITLE	Intermittent Androgen deprivation Therapy in the era of AR pathway inhibitors; a phase 3 pragmatic randomized trial (DE-ESCALATE)
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof Paul Donnellan

✓ INCLUSION CRITERIA

Patient treated with ADT (LHRH agonist or antagonist) and an ARpI for mHSPC for 6-12 months and presenting with a PSA \leq 0.2 ng/mL

✗ EXCLUSION CRITERIA

- Patients with M1 on modern imaging technique (PET, PSMA or whole body MRI) for who radiation and hormone therapy is planned.
- Underwent orchidectomy
- Prior or concurrent malignancy that may interfere with safety or efficacy assessment
- Patients who received a systemic anti prostate cancer treatment not approved by the EMA with MAB or radical prostatectomy of M1 disease

STUDY COORDINATORS

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HAEMATOLOGY TRIALS

11 trials in this section

17.MajesTEC-4

FULL TITLE	Phase 3 Study of Teclistamab + Lenalidomide, and Teclistamab Alone, vs Lenalidomide Alone in Newly Diagnosed Multiple Myeloma as Maintenance Therapy after Autologous Stem Cell Transplantation
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof Janusz Krawczyk; Dr Muhammad Fawad Khan

✓ INCLUSION CRITERIA

- Aged 18+ with newly diagnosed symptomatic multiple myeloma per IMWG criteria; received 4–6 cycles of 3- or 4-drug induction therapy including a proteasome inhibitor and/or IMiD (with or without anti-CD38 mAb) and a single or tandem ASCT
- Only one prior line of therapy and achieved at least partial response (≥PR) per IMWG 2016 criteria
- High-dose chemotherapy and ASCT within 12 months of start of induction; within 6 months of the last ASCT at randomisation (sponsor approval required)
- Must not have received any maintenance therapy
- ECOG 0–2 at screening and immediately before start of treatment

✗ EXCLUSION CRITERIA

- Previous gene-modified adoptive cell therapy (e.g. CAR-T, NK cells)
- History of allogeneic SCT or prior organ transplant
- Progressive disease per IMWG 2016 at any time prior to randomisation
- Radiotherapy within 14 days, or focal radiation within 7 days, of C1D1
- Ongoing MDS or other B-cell malignancy; any other high-risk or active malignancy (exceptions per protocol)
- PCL, smouldering MM, WM, POEMS syndrome, or light-chain amyloidosis without underlying symptomatic myeloma
- CNS involvement or significant cardiac conditions
- Investigational drug or invasive device within 4 weeks or 5 PK half-lives before C1D1

STUDY COORDINATORS

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18.SUCCESSOR

FULL TITLE	Two-stage, Randomised, Multicentre, Open-label Phase 3 Study Comparing Mezigdomide + Bortezomib + Dexamethasone (MeziVd) vs Pomalidomide + Bortezomib + Dexamethasone (PvD) in Relapsed/Refractory Multiple Myeloma after 1–3 Prior Lines with Prior Lenalidomide Exposure
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof Janusz Krawczyk; Dr Muhammad Fawad Khan

✓ INCLUSION CRITERIA

- Aged 18+ with MM diagnosis and measurable disease
- 1–3 prior lines of anti-MM therapy including a lenalidomide-containing regimen, with ≥MR to at least one prior therapy
- Documented disease progression during or after last anti-myeloma regimen
- ECOG 0, 1, or 2

✗ EXCLUSION CRITERIA

- Progression during or within 60 days of last proteasome inhibitor dose (limited exceptions — see protocol)
- Prior bortezomib where best response was less than minimal response, or discontinued bortezomib due to toxicity
- Prior treatment with mezigdomide or pomalidomide
- Investigational agents within 28 days or 5 half-lives (whichever is shorter) of study start
- Plasmapheresis within 28 days; major surgery within 28 days; local-palliative-only radiation within 14 days; any systemic anti-myeloma drug within 14 days
- Prior allogeneic SCT at any time, or autologous SCT within 12 weeks of start
- History of PCL, WM, POEMS syndrome, or light-chain amyloidosis
- Known CNS myeloma involvement
- GI disease or surgery that may significantly alter oral absorption
- Prior malignancy other than MM unless disease-free ≥3 years (exceptions per protocol)
- Immunosuppressive medication within 14 days of start (exceptions per protocol)
- Clinically significant cardiac disease

STUDY COORDINATORS

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19.DREAMM-10

FULL TITLE	Phase 3 Randomised Open-label Study of Belantamab Mafodotin + Lenalidomide + Dexamethasone vs Daratumumab + Lenalidomide + Dexamethasone in Newly Diagnosed Multiple Myeloma Ineligible for Autologous Stem Cell Transplant
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof Janusz Krawczyk; Dr Muhammad Fawad Khan

✓ INCLUSION CRITERIA

- Aged 18+ with newly diagnosed MM per IMWG criteria
- At least one aspect of measurable disease
- Not a candidate for high-dose chemotherapy with ASCT due to age restriction or comorbidities likely to affect tolerability
- ECOG 0–2

✗ EXCLUSION CRITERIA

- Systemic AL amyloidosis, WM, POEMS, or primary PCL
- Any prior systemic therapy for MM or smouldering MM
- Meningeal or CNS involvement with MM
- Major surgery within 2 weeks prior to first study dose
- Current active liver or biliary disease
- Previous or concurrent malignancies other than MM (exceptions per protocol)
- Evidence of cardiovascular risk
- Current corneal epithelial disease (except mild punctate keratopathy)
- Plasmapheresis within 7 days prior to first study dose
- Live or live-attenuated vaccine within 30 days prior to first dose of belantamab mafodotin

STUDY COORDINATORS

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20.EBMT-LWP-2021-N-02

FULL TITLE	Use of Brentuximab Vedotin and/or Checkpoint Inhibitors as a Bridge to Autologous Transplantation in Hodgkin's Lymphoma
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof Amjad Hayat

✓ INCLUSION CRITERIA

- Aged 18+
- Diagnosis of classical Hodgkin's Lymphoma
- Decision to use brentuximab vedotin and/or checkpoint-inhibitor-based salvage therapy as bridge to autologous SCT

✗ EXCLUSION CRITERIA

- Does not meet the inclusion criteria above

STUDY COORDINATORS

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21.CLL18

FULL TITLE	Phase 3 Multicentre Randomised Prospective Open-label Trial of Fixed-duration Venetoclax/Obinutuzumab vs Fixed-duration Venetoclax/Pirtobrutinib vs MRD-guided Venetoclax/Pirtobrutinib in Previously Untreated CLL/SLL
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof Amjad Hayat

✓ INCLUSION CRITERIA

- Documented CLL/SLL requiring treatment per iwCLL criteria, with CLL phenotype cell count $>10^{-2}$ by flow cytometry at screening
- Adequate bone marrow function: platelets $\geq 25 \times 10^9/L$ (unless disease-related, in which case $\geq 10,000/\mu L$ without transfusion in last 7 days)
- Adequate renal function (creatinine); adequate liver function
- Negative serology for hepatitis B and C (HCV-RNA PCR) and HIV within 6 weeks prior to registration
- Aged 18+; ECOG 0–2; life expectancy ≥ 6 months
- Able and willing to provide written informed consent

✗ EXCLUSION CRITERIA

- Any prior CLL/SLL-specific therapy, except corticosteroids
- Decompensated auto-immune cytopenia
- Suspected transformation of CLL/SLL (e.g. Richter transformation) or CNS involvement
- Suspected progressive multifocal leukoencephalopathy (PML)
- Other malignancy unless in remission and unlikely to affect life expectancy (curatively treated non-melanoma skin cancer, or other cancers treated curatively ≥ 1 year ago without progression and not requiring systemic therapy — anti-hormonal therapy permitted)
- Active infection requiring systemic treatment, including HIV, HBV, and HCV

STUDY COORDINATORS

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22.BGB 114-17-303

FULL TITLE	Phase 3 Randomised Open-label Multicentre Study of Sonrotoclax + Anti-CD20 Antibody Therapies vs Venetoclax + Rituximab in Relapsed/Refractory CLL/SLL
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Dr Jill Coll

✓ INCLUSION CRITERIA

- Aged 18+ with confirmed CLL/SLL per iwCLL 2018 criteria (Hallek et al. 2018)
- At least one prior therapy for CLL/SLL, with at least 2 cycles received per line
- For prior BCL2i: only eligible if received in first line with fixed-duration therapy, remission ≥ 3 years, and ≥ 2 years between last BCL2i dose and screening
- Indications for CLL/SLL therapy met per iwCLL 2018 (with minor protocol modifications)
- ECOG 0–2
- Adequate marrow function: ANC $\geq 1.0 \times 10^9/L$ (≥ 0.75 with bone marrow involvement, no growth factor in past 7 days); platelets $\geq 75 \times 10^9/L$; haemoglobin >75 g/L
- Adequate liver and renal function; life expectancy >6 months

✗ EXCLUSION CRITERIA

- Active HBV, HCV, or HIV at study start
- Active prolymphocytic leukaemia or suspected Richter's transformation
- Clinically significant ongoing cardiovascular or pulmonary disease
- CNS involvement by CLL/SLL

STUDY COORDINATORSDorota Matczuk — Dorota.Matczuk@hse.ieKatherine Cussen — Katherine.Cussen@hse.ie

23. BCNI Biobank

FULL TITLE	Blood Cancer Biobank Ireland (BCBI) — Sample Collection and Management
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof Janusz Krawczyk

✓ INCLUSION CRITERIA

- All newly diagnosed CLL, AML, and Multiple Myeloma participants who have not yet received any treatment

✗ EXCLUSION CRITERIA

- Does not meet the inclusion criteria above

STUDY COORDINATORS

Contact site PI directly.

24. GEM

FULL TITLE	The Impact of Genetic Expression in Multiple Myeloma
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof Janusz Krawczyk

✓ INCLUSION CRITERIA

- All newly diagnosed Multiple Myeloma participants eligible for autologous stem cell transplant

✗ EXCLUSION CRITERIA

- Does not meet the inclusion criteria above

STUDY COORDINATORS

Contact site PI directly.

25.EMN39

FULL TITLE	A Randomized, Open-Label, Controlled Phase 3 Study Comparing Daratumumab, Lenalidomide and Dexamethasone Induction followed by Linvoseltamab Versus continued Daratumumab, Lenalidomide, and Dexamethasone in Newly Diagnosed Transplant Ineligible Multiple Myeloma Patients
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof. Janusz Krawczyk

✓ INCLUSION CRITERIA

- Adults (≥ 18 years) with newly diagnosed, symptomatic multiple myeloma per IMWG criteria
- Transplant-ineligible due to advanced age and/or significant comorbidities
- Measurable disease per IMWG criteria
- ECOG performance status 0–2

✗ EXCLUSION CRITERIA

- Frail patients (IMWG Frailty Index ≥ 2), except limited cases based on age alone
- Patients eligible for transplant who defer ASCT by preference only
- Non-secretory myeloma, plasma cell leukemia, amyloidosis, or POEMS syndrome
- Prior systemic therapy for MGUS/SMM/MM

STUDY COORDINATORS

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Trials Team: 087 2846991

26.R458-ONC-2257

FULL TITLE	Phase 2 Dose-Ranging and Interception Study of Linvoseltamab in Patients with High-Risk Monoclonal Gammopathy of Undetermined Significance or Non-High-Risk Smoldering Multiple Myeloma
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof. Janusz Krawczyk

✓ INCLUSION CRITERIA

- Adults ≥ 18 years with high-risk MGUS or non-high-risk smoldering multiple myeloma (NHR-SMM)
- ECOG performance status ≤ 1
- Adequate organ function (ANC, platelets, bilirubin, AST/ALT, eGFR within limits)

✗ EXCLUSION CRITERIA

- High-risk SMM by Mayo 20-2-20 criteria or IMWG risk score ≥ 9
- Presence of myeloma-defining SLiM-CRAB features
- Symptomatic MM, amyloidosis, Waldenström macroglobulinemia, or solitary plasmacytoma
- Prior therapy for plasma cell disorders

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27.RADAR

FULL TITLE	A Randomised Phase III Study with a PET Response Adapted Design Comparing ABVD +/- ISRT with A2VD +/- ISRT in Patients with Previously Untreated Stage IA/IIA Hodgkin Lymphoma
SITE	Galway University Hospital
PRINCIPAL INVESTIGATOR	Prof. Amjad Hayat

✓ INCLUSION CRITERIA

- Patients aged 16–69 years with histologically confirmed classical Hodgkin lymphoma
- Stage I–II supradiaphragmatic disease without mediastinal bulk or B symptoms
- ECOG performance status 0–2; no prior treatment for Hodgkin lymphoma
- Eligible for anthracycline-based chemotherapy with adequate organ/marrow function

✗ EXCLUSION CRITERIA

- Prior Hodgkin lymphoma treatment (except short-course corticosteroids)
- Infradiaphragmatic disease or nodular lymphocyte-predominant Hodgkin lymphoma
- Non-FDG-avid disease on baseline PET
- Active HIV, hepatitis B, or hepatitis C infection

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