

Clinical trial of whether AZD5069 combined with immunotherapy (durvalumab) is effective for patients with advanced primary liver cancer

Submission date 14/02/2022	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/03/2022	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/04/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English Summary

Background and study aims

Liver cancer is increasingly common and there are currently few drug treatments that are proven to be effective in patients with advanced disease. There is some evidence that drugs that target a molecule known as PDL-1, such as durvalumab, can enable the immune system to eradicate cancer cells and have some activity in shrinking liver cancer, but are not sufficient on their own to improve survival in patients with advanced disease. Experiments in the laboratory suggest that targeting immune cells known as chemokines with a drug called AZD5069 can increase the effects of anti-PDL-1 antibody therapy on liver cancer. The aim of this study is to find the recommended dose of AZD5069 when given in combination with durvalumab in patients with liver cancer and determine if this treatment is effective at shrinking liver cancers.

Who can participate?

Patients aged 18 years or over with advanced liver cancer that is not suitable for surgery

What does the study involve?

Participants will take AZD5069 tablets twice a day continuously and will receive a drip of durvalumab once every 4 weeks. Treatment will continue for as long as patients are benefiting from and tolerating the treatment up to a maximum of 2 years. AZD5069 treatment will be received up to a maximum of one year to “prime” the immune system, that is, to sensitize it to durvalumab. Durvalumab treatment will be administered up to a maximum of 2 years. Frequent blood samples will be taken to confirm that this regimen is safe and CT scans will be performed every 8 weeks to look at the effect of treatment on the cancer. A biopsy (sample) of the liver tumour will also be performed before starting treatment and once during the first 4-week treatment course which may help us to determine how best to use these two drugs in the future.

What are the possible benefits and risks of participating?

The potential benefit to participants is that this treatment could be effective at reducing the size of the tumours, improving for how long the cancer can be controlled, and improving patient survival. The main risks are the potential side effects of the treatment which include low white blood cell count (and infections) and the side effects of durvalumab, which can cause

inflammation of various body organs including skin rash, inflammatory bowel effects, liver inflammation, and deficiency of certain hormones (e.g. thyroid). These side effects usually resolve with steroid treatment.

Where is the study run from?

Cancer Research UK Glasgow Clinical Trials Unit in NHS Greater Glasgow and Clyde (UK)

When is the study starting and how long is it expected to run for?

February 2020 to June 2027

Who is funding the study?

Cancer Research UK

Who is the main contact?

1. Prof. Jeffry Evans, j.evans@crukscotlandinstitute.ac.uk

2. Claire Cantley, claire.cantley@glasgow.ac.uk

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-azd5069-and-durvalumab-for-cancer-that-started-in-the-liver-cubic>

Contact information

Type(s)

Scientific

Contact name

Prof Jeffry Evans

Contact details

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Additional identifiers

EudraCT/CTIS number

2020-003346-36

IRAS number

287628

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CUBIC-2021, IRAS 287628

Study information

Scientific Title

CUBIC: a Phase I/II study of the CXCR2 inhibitor, AZD5069, in combination with durvalumab (MEDI4736), in patients with advanced hepatocellular carcinoma

Acronym

CUBIC

Study hypothesis

AZD5069, by inhibiting CXCR2 and, therefore, depleting myeloid-derived suppressor cells (MDSC) and neutrophils in the liver tumour can enhance the anti-tumour efficacy of PD-L1 pathway antibodies, leading to improved overall survival.

The optimal dose of AZD5069 in combination with durvalumab has been determined in advanced solid tumours (80mgs bid). However, it is appropriate to confirm this specifically in patients with liver cancer, who have abnormal liver function, as AZD5069 is mainly metabolised in the liver.

This will be followed by a dose-expansion (Phase II) part of the study to determine the efficacy of this combination in patients with advanced liver cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 01/02/2021, Tyne and Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048306, +44 (0)2071048285, +44 (0)2071048265; tyneandwearsouth.rec@hra.nhs.uk), REC ref: 21/NE/0023

Study design

Multi-centre Phase I/II study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Condition

Advanced liver cancer

Interventions

Current interventions as of 08/04/2025:

Patients will be identified from Oncology or Hepatology Clinics as per local practice. AZD5069 will be administered orally, twice daily, on a continuous administration schedule starting on day 1 of cycle 1 (4-week cycles). Durvalumab will be administered at a fixed dose of 1500 mg by intravenous infusion on day 1 of each 4-week cycle (starting on cycle 1). Treatment will be continued at 4-weekly cycles for all patients until the patient's decision to withdraw, progressive disease, unacceptable toxicity, or at the investigator's discretion. Treatment with AZD5069 can continue for up to 1 year and durvalumab can continue for up to a maximum of 2 years, that is, patients who continue on study treatment beyond 1 year will receive durvalumab monotherapy with the AZD5069 used as a "priming" regimen for the first year of study treatment. If either AZD5069 or durvalumab need to be discontinued due to specific drug-related toxicities, the other drug can be continued until the criteria for stopping have been met. Patients will continue to be followed up following discontinuation of study therapy (regardless of the reason, unless consent is withdrawn) to determine progression-free and overall survival.

The starting dose is AZD5069 40 mg. The dose levels are as follows:

Dose level -1: AZD5069 20 mg and durvalumab 1500 mg

Dose level 1: AZD5069 40 mg and durvalumab 1500 mg

Dose level 2: AZD5069 60 mg and durvalumab 1500 mg

Dose level 3: AZD5069 80 mg and durvalumab 1500 mg

Previous interventions:

Patients will be identified from Oncology or Hepatology Clinics as per local practice. AZD5069 will be administered orally, twice daily, on a continuous administration schedule starting on day 1 of cycle 1 (4-week cycles). Durvalumab will be administered at a fixed dose of 1500 mg by intravenous infusion on day 1 of each 4-week cycle (starting on cycle 1). Treatment will be continued at 4-weekly cycles for all patients until the patient's decision to withdraw, progressive disease, unacceptable toxicity, or at the investigator's discretion, and up to a maximum of 2 years for durvalumab and AZD5069. Patients will continue to be followed up following discontinuation of study treatment (regardless of the reason, unless consent is withdrawn) to determine progression-free and overall survival.

The starting dose is AZD5069 40 mg. The dose levels are as follows:

Dose level -1: AZD5069 20 mg and durvalumab 1500 mg

Dose level 1: AZD5069 40 mg and durvalumab 1500 mg

Dose level 2: AZD5069 60 mg and durvalumab 1500 mg

Dose level 3: AZD5069 80 mg and durvalumab 1500 mg

Intervention Type

Drug

Phase

Phase I/II

Drug/device/biological/vaccine name(s)

AZD5069, durvalumab (MEDI4736)

Primary outcome measure

Dose Escalation/Phase I:

The recommended dose of AZD5069 when administered in combination with durvalumab in patients with advanced hepatocellular cancer (liver cancer). This will be defined by the maximum tolerated dose (MTD), determined by dose-limiting toxicities as measured by clinical and laboratory toxicities (NCI-CTC AE version 5) during the first 4-week cycle of treatment.

Dose Expansion/Phase II:

The overall objective response rate as determined by Response Evaluation Criteria in Solid Tumours (RECIST)1.1 in patients with advanced hepatocellular cancer. CT scans will be performed every 8 weeks (every 12 weeks after year 1) until disease progression.

Secondary outcome measures

1. The safety and tolerability of AZD5069 and durvalumab, measured by NCI-CTC AE version 5. Toxicity is assessed prior to treatment and throughout treatment, up to 90 days after continuation of trial medication.
2. Time to radiological progression, measured by RECIST 1.1 CT scans will be performed every 8 weeks (every 12 weeks after year 1) until disease progression.
3. Progression-free survival, determined as the time from patient registration to subsequent radiological disease progression or death). CT scans will be performed every 8 weeks (every 12 weeks after year 1) until disease progression.
4. Overall survival (time from registration to death) will be summarised at varying timepoints, along with medians using Kaplan-Meier survival curves on completion of the study. Patients are followed-up from time of registration to death, withdrawal of consent or the end of the trial, whichever occurs first.

Overall study start date

01/02/2020

Overall study end date

30/06/2027

Eligibility

Participant inclusion criteria

Current inclusion criteria as of 08/04/2025:

1. Histologically or cytologically confirmed hepatocellular carcinoma that is not suitable for surgery (with or without transplantation) or locoregional therapies
 2. Patients with evidence of background liver disease or without evidence of underlying liver disease will be eligible
 3. Patients who have either (a) not received prior systemic anti-cancer therapy; or (b) who have progressed on, or who are intolerant to, no more than one line or prior therapy with either sorafenib or lenvatinib (patients who change 1st-line tyrosine kinase therapy from sorafenib to lenvatinib, and vice versa, within 2 months of starting treatment because of toxicity, and without evidence of disease progression, will be considered as having had one line of therapy), or an anti-PD(L)-1 antibody either as monotherapy or in combination with bevacizumab, a CTLA-4 antibody, or lenvatinib. Patients who developed > grade 2 immune-mediated toxicity, or who discontinued treatment due to immune-mediated toxicity, or who progressed within the first 12 weeks of previous immunotherapy treatment will be excluded. However, patients who developed immune-mediated endocrinopathy that has resolved and are on hormone replacement therapy are eligible.
- Patients who have received pre-operative (neo-adjuvant) systemic therapy followed by surgery

with curative intent, with no macroscopic or microscopic residual disease, and in whom recurrent disease occurs >12 months after surgical resection, will be considered to be treatment-naïve for unresectable HCC

4. Able to undergo a pre-treatment and on-treatment biopsy of a liver tumour and of non-tumour liver for pharmacodynamic and predictive biomarker studies

5. ECOG performance status ≤ 1 (Appendix II)

6. Age ≥ 18 years

7. Measurable disease by RECIST 1.1. Patients who have previously been treated with TACE or ablation will be eligible provided there is either a new measurable lesion (that has not been treated with ablation/TACE) or a new, reproducibly measurable, hyper-vascular area with washout within a previously treated lesion or area

8. Estimated life expectancy greater than 3 months

9. Adequate haematological function as defined by:

9.1. Haemoglobin (Hb) ≥ 90 g/l

9.2. Neutrophil Count $\geq 1.5 \times 10^9$ /l

9.3. Platelets $\geq 75 \times 10^9$ /l

10. Child–Pugh Score A (≤ 6) [Appendix VIII]

11. Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) $< 3.0 \times \text{ULN}$

12. Bilirubin < 34 $\mu\text{mol/l}$

13. Adequate renal function with creatinine clearance / glomerular filtration rate > 50 ml/min as calculated by local standard practice

14. Ability to swallow oral medication

15. Written informed consent prior to performing any study-related procedures

16. Patients with past or ongoing HCV infection will be eligible for the study. Patients who have been treated for HCV infection must have completed their treatment at least 1 month prior to starting trial therapy

17. Patients with controlled hepatitis B will be eligible as long as they meet the following criteria:

17.1. Antiviral therapy for HBV must be given for at least 4 weeks and HBV viral load must be less than 500 IU/ml prior to the first dose of the study drug. Patients on active HBV therapy with viral loads under 500 IU/ml should stay on the same therapy throughout the study treatment.

17.2. Patients who are positive for anti-hepatitis B core antibody HBc, negative for hepatitis B surface antigen (HBsAg), and negative or positive for anti-hepatitis B surface antibody (HBs), and who have an HBV viral load under 500 IU/ml, do not require HBV anti-viral prophylaxis

Previous inclusion criteria:

1. Histologically or cytologically confirmed hepatocellular carcinoma that is not suitable for surgery (with or without transplantation) or locoregional therapies

2. Patients with evidence of background liver disease or without evidence of underlying liver disease will be eligible

3. Patients who have either (a) not received prior systemic anti-cancer therapy; or (b) who have progressed on, or who are intolerant to, no more than one line or prior therapy with either sorafenib or lenvatinib (patients who change 1st - line tyrosine kinase therapy from sorafenib to lenvatinib, and vice versa, within 2 months of starting treatment because of toxicity, and without evidence of disease progression, will be considered as having had one line of therapy), or an anti-PD(L)-1 antibody either as monotherapy or in combination with bevacizumab, a CTLA-4 antibody, or lenvatinib. Patients who developed $>$ grade 2 immune-mediated toxicity, or who discontinued treatment due to immune-mediated toxicity, or who progressed within the first 12 weeks of previous immunotherapy treatment will be excluded.

4. Willing to undergo a pre-treatment biopsy of tumour and of non-tumour liver for pharmacodynamic and predictive biomarker studies

5. ECOG performance status ≤ 1 (Appendix II)

6. Age ≥ 18 years

7. Measurable disease by RECIST 1.1. Patients who have previously been treated with TACE or ablation will be eligible provided there is either a new measurable lesion (that has not been treated with ablation/TACE) or a new, reproducibly measurable, hyper-vascular area with washout within a previously treated lesion or area
8. Estimated life expectancy greater than 3 months
9. Adequate haematological function as defined by:
 - 9.1. Haemoglobin (Hb) ≥ 90 g/l
 - 9.2. Neutrophil Count $\geq 1.5 \times 10^9$ /l
 - 9.3. Platelets $\geq 75 \times 10^9$ /l
10. Child – Pugh Score A (≤ 6) [Appendix VIII]
11. Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) $< 3.0 \times$ ULN
12. Bilirubin < 34 μ mol/l
13. Adequate renal function with creatinine clearance / glomerular filtration rate > 50 ml/min as calculated by local standard practice
14. Ability to swallow oral medication
15. Able to comply with study procedures including on-treatment biopsies of tumour and non-liver tumour in patients recruited into the dose expansion cohorts
16. Written informed consent prior to performing any study-related procedures
17. Patients with past or ongoing HCV infection will be eligible for the study. Patients who have been treated for HCV infection must have completed their treatment at least 1 month prior to starting trial therapy
18. Patients with controlled hepatitis B will be eligible as long as they meet the following criteria:
 - 18.1. Antiviral therapy for HBV must be given for at least 4 weeks and HBV viral load must be less than 500 IU/ml prior to the first dose of the study drug. Patients on active HBV therapy with viral loads under 500 IU/ml should stay on the same therapy throughout the study treatment.
 - 18.2. Patients who are positive for anti-hepatitis B core antibody HBc, negative for hepatitis B surface antigen (HBsAg), and negative or positive for anti-hepatitis B surface antibody (HBs), and who have an HBV viral load under 500 IU/ml, do not require HBV anti-viral prophylaxis

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Phase I dose escalation - up to a maximum of 21 patients. Phase II dose expansion - 35 patients (of which, 6-9 patients will be counted from Phase I)

Participant exclusion criteria

Current exclusion criteria as of 08/04/2025:

1. Pregnant or breastfeeding women
2. Women of childbearing potential* and men with female partners of childbearing potential who are not willing to use two forms of contraception, including one highly effective method. Men with pregnant or breastfeeding partners should be advised to use barrier method

contraception to prevent exposure to the foetus or neonate during treatment.

*A woman is considered of childbearing potential (WOCBP) i.e. fertile, following menarche and until becoming post-menopausal unless permanently sterile. Permanent sterilisation methods include hysterectomy, bilateral salpingectomy and bilateral oophorectomy. A postmenopausal state is defined as no menses for 12 months without an alternative medical cause.

3. Cardiovascular disease defined as Stage II to IV congestive heart failure (CHF) as determined by the New York Heart Association (NYHA) classification system, or history of myocardial infarction (MI), or cardiac arrhythmia associated with haemodynamic instability, or unstable angina, or cerebral vascular accident, or transient ischemia, if any have occurred within the previous 12 months prior to study treatment.

4. Any other serious medical or psychiatric disorder that would be, in the opinion of the investigator, a contraindication to either the trial procedures or to therapy with AZD5069 or durvalumab

5. Patients with a lack of physical integrity of the GI tract leading to a malabsorption syndrome or intestinal obstruction that would impair the administration and absorption of oral therapy

6. Any previous > grade 2 toxicity or discontinuation of therapy due to immune-mediated toxicity with an immune checkpoint inhibitor. Patients who developed immune-mediated endocrinopathy that has resolved and are on hormone replacement therapy will be considered eligible.

7. Major surgery within 14 days of starting study treatment and patients must have recovered from any effects of major surgery

8. Patients with a known hypersensitivity to AZD5069 or durvalumab or any of the excipients of the products

9. Current or prior use of immunosuppressive medication within 14 days before the first dose of durvalumab. The following are exceptions to this criterion:

9.1. Intranasal, inhaled, or topical steroids; or local steroid injections (e.g., intra-articular injection)

9.2. Systemic corticosteroids at physiologic doses not to exceed 10 mg/day of prednisolone or equivalent

9.3. Steroids as premedication for hypersensitivity reactions (e.g., CT scan premedication) and chemotherapy-induced nausea and vomiting

10. History of allogenic organ transplant

11. Active autoimmune disorders, or prior documented severe autoimmune or inflammatory disorders requiring immunosuppressive treatment (including inflammatory bowel disease [e.g., colitis, Crohn's disease], diverticulitis with the exception of diverticulosis, coeliac disease, irritable bowel syndrome, or other serious gastrointestinal chronic conditions associated with diarrhoea); systemic lupus erythematosus; Wegener syndrome (granulomatosis with polyangiitis), Graves' disease; rheumatoid arthritis, hypophysitis, uveitis, etc. The following are exceptions to this criterion:

11.1. Patients with vitiligo or alopecia

11.2. Diabetes mellitus type I or resolved childhood asthma/atopy

11.3. Patients with hypothyroidism (e.g., following Hashimoto syndrome) stable on hormone replacement

11.4. Any chronic skin condition that does not require systemic therapy

11.5. Patients with coeliac disease controlled by diet alone

12. Receipt of any investigational anticancer therapy within 28 days or 5 half-lives, whichever is longer, prior to the first dose of study treatment.

13. Concurrent enrolment in another clinical study unless it is an observational (non-interventional) clinical study or during the follow-up period of an interventional study.

14. Receipt of the last dose of an approved (marketed) anticancer therapy (chemotherapy, targeted therapy, biologic therapy, monoclonal antibodies etc) or radiotherapy within 28 days prior to the first dose of study treatment

15. Other malignancy within 5 years except for non-invasive malignancies such as cervical carcinoma in situ, non-melanoma carcinoma of the skin, prostate cancer or ductal carcinoma in situ of the breast that has/have been surgically cured
16. Mean QT interval corrected for heart rate using Fridericia's formula (QTcF) ≥ 470 ms calculated from three ECG reports (within 5 minutes at least 1 minute apart).
17. History of active primary immunodeficiency
18. History of (non-infectious) interstitial lung disease or pneumonitis that required steroids or current pneumonitis.
19. Patients with an active infection requiring systemic therapy.
20. Receipt of live attenuated vaccine within 30 days prior to the first dose of study therapy. Note: patients, if enrolled, should not receive a live attenuated vaccine during the study and up to 30 days after the last dose of any investigational products (IPs).
21. Current or prior use of the following concomitant medication within 14 days before the first dose of AZD5069: Strong or moderate inducers or inhibitors of CYP3A4; CYP2C9 substrates with a narrow therapeutic index (e.g. warfarin and coumarin derivatives); Pgp substrates with a narrow therapeutic index (e.g. digoxin, dabigatran); sensitive CYP2B6 substrates; BCRP substrates that reduce blood neutrophils or herbal supplements (see <https://drug-interactions.medicine.iu.edu/MainTable.aspx>).
22. Patients who weigh ≤ 30 kg will be excluded

Previous exclusion criteria:

1. Pregnant or breastfeeding women
2. Women of childbearing potential* and men with female partners of childbearing potential who are not willing to use two forms of contraception, including one highly effective method. Men with pregnant or breastfeeding partners should be advised to use barrier method contraception to prevent exposure to the foetus or neonate during treatment.
*A woman is considered of childbearing potential (WOCBP) i.e. fertile, following menarche and until becoming post-menopausal unless permanently sterile. Permanent sterilisation methods include hysterectomy, bilateral salpingectomy and bilateral oophorectomy. A postmenopausal state is defined as no menses for 12 months without an alternative medical cause.
3. Cardiovascular disease defined as Stage II to IV congestive heart failure (CHF) as determined by the New York Heart Association (NYHA) classification system, or history of myocardial infarction (MI), or cardiac arrhythmia associated with haemodynamic instability, or unstable angina, or cerebral vascular accident, or transient ischemia, if any have occurred within the previous 12 months prior to study treatment.
4. Any other serious medical or psychiatric disorder that would be, in the opinion of the investigator, a contraindication to either the trial procedures or to therapy with AZD5069 or durvalumab
5. Patients with a lack of physical integrity of the GI tract leading to a malabsorption syndrome or intestinal obstruction that would impair the administration and absorption of oral therapy
6. Any previous > grade 2 toxicity or discontinuation of therapy due to immune-mediated toxicity with an immune checkpoint inhibitor
7. Major surgery within 14 days of starting study treatment and patients must have recovered from any effects of major surgery
8. Patients with a known hypersensitivity to AZD5069 or durvalumab or any of the excipients of the products
9. Current or prior use of immunosuppressive medication within 14 days before the first dose of durvalumab. The following are exceptions to this criterion:
 - 9.1. Intranasal, inhaled, or topical steroids; or local steroid injections (e.g., intra-articular injection)
 - 9.2. Systemic corticosteroids at physiologic doses not to exceed 10 mg/day of prednisolone or equivalent

- 9.3. Steroids as premedication for hypersensitivity reactions (e.g., CT scan premedication) and chemotherapy-induced nausea and vomiting
10. History of allogenic organ transplant
11. Active autoimmune disorders, or prior documented severe autoimmune or inflammatory disorders requiring immunosuppressive treatment (including inflammatory bowel disease [e.g., colitis, Crohn's disease], diverticulitis with the exception of diverticulosis, coeliac disease, irritable bowel syndrome, or other serious gastrointestinal chronic conditions associated with diarrhoea); systemic lupus erythematosus; Wegener syndrome (granulomatosis with polyangiitis), Graves' disease; rheumatoid arthritis, hypophysitis, uveitis, etc. The following are exceptions to this criterion:
- 11.1. Patients with vitiligo or alopecia
- 11.2. Diabetes mellitus type I or resolved childhood asthma/atopy
- 11.3. Patients with hypothyroidism (e.g., following Hashimoto syndrome) stable on hormone replacement
- 11.4. Any chronic skin condition that does not require systemic therapy
- 11.5. Patients with coeliac disease controlled by diet alone
12. Receipt of any investigational anticancer therapy within 28 days or 5 half-lives, whichever is longer, prior to the first dose of study treatment.
13. Concurrent enrolment in another clinical study unless it is an observational (non-interventional) clinical study or during the follow-up period of an interventional study.
14. Receipt of the last dose of an approved (marketed) anticancer therapy (chemotherapy, targeted therapy, biologic therapy, monoclonal antibodies etc) or radiotherapy within 28 days prior to the first dose of study treatment
15. Other malignancy within 5 years except for non-invasive malignancies such as cervical carcinoma in situ, non-melanoma carcinoma of the skin, prostate cancer or ductal carcinoma in situ of the breast that has/have been surgically cured
16. Mean QT interval corrected for heart rate using Fridericia's formula (QTcF) ≥ 470 ms calculated from three ECG reports (within 5 minutes at least 1 minute apart).
17. History of active primary immunodeficiency
18. History of (non-infectious) interstitial lung disease or pneumonitis that required steroids or current pneumonitis.
19. Patients with an active infection requiring systemic therapy.
20. Receipt of live attenuated vaccine within 30 days prior to the first dose of study therapy. Note: patients, if enrolled, should not receive a live attenuated vaccine during the study and up to 30 days after the last dose of any investigational products (IPs).
21. Current or prior use of the following concomitant medication within 14 days before the first dose of AZD5069: Strong or moderate inducers or inhibitors of CYP3A4; CYP2C9 substrates with a narrow therapeutic index (e.g. warfarin and coumarin derivatives); Pgp substrates with a narrow therapeutic index (e.g. digoxin, dabigatran); sensitive CYP2B6 substrates; BCRP substrates that reduce blood neutrophils or herbal supplements (see <https://drug-interactions.medicine.iu.edu/MainTable.aspx>).
22. Patients who weigh ≤ 30 kg will be excluded

Recruitment start date

29/04/2022

Recruitment end date

12/01/2026

Locations

Countries of recruitment

England

Scotland

United Kingdom

Study participating centre

Beatson West of Scotland Cancer Centre

1053 Great Western Road

Glasgow

United Kingdom

G12 0YN

Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Dept of Oncology, Addenbrooke's Hospital

Cambridge

United Kingdom

CB2 0QQ

Study participating centre

The Christie NHS Foundation Trust

Wilmslow Road

Manchester

United Kingdom

M20 4BX

Study participating centre

The Clatterbridge Cancer Centre NHS Foundation Trust

Clatterbridge Road

Bebington

Wirral

United Kingdom

CH63 4JY

Study participating centre

University Hospitals Birmingham NHS Foundation Trust

Edgbaston

Birmingham
United Kingdom
B15 2TT

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
St James' University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Northern Centre for Cancer Care
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Hammersmith Hospital
Du Cane Road
Hammersmith
London
United Kingdom
W12 0HS

Study participating centre
Kings College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Sponsor information

Organisation

NHS Greater Glasgow and Clyde

Sponsor details

J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road
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United Kingdom
G12 0YX
+44 (0)141 314 4001
joanne.mcgarra@ggc.scot.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.nhs-ggc.org.uk/>

ROR

<https://ror.org/05kdz4d87>

Organisation

University of Glasgow

Sponsor details

University Avenue
Glasgow
Scotland
United Kingdom
G12 8QQ
+44 (0)141 330 4539
debra.stuart@glasgow.ac.uk

Sponsor type

University/education

Website

<http://www.gla.ac.uk/>

ROR

<https://ror.org/00vtgdb53>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

30/06/2028

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No