

# SeluDex: an international trial of selumetinib in combination with dexamethasone for the treatment of acute lymphoblastic leukaemia

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<b>Registration date</b> 23/05/2018	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/02/2026	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-selumetinib-and-dexamethasone-for-acute-lymphoblastic-leukaemia-seludex>

## Contact information

### Type(s)

Public

### Contact name

Dr Joshua Savage

### Contact details

Cancer Research UK Clinical Trials Unit (CRCTU)  
Robert Aitken Clinical Research Building  
Institute of Cancer and Genomic Sciences  
The University of Birmingham  
Vincent Drive  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TT  
+44 (0)121 414 6754  
seludex@trials.bham.ac.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

2016-003904-29

**ClinicalTrials.gov (NCT)**

NCT03705507

**Protocol serial number**

RG\_16-186

**Central Portfolio Management System (CPMS)**

33990

## Study information

### Scientific Title

International phase I/II expansion trial of the MEK inhibitor selumetinib in combination with dexamethasone for the treatment of relapsed/refractory RAS-pathway mutated paediatric and adult acute lymphoblastic leukaemia

### Acronym

SeluDex

### Study objectives

The purpose of this trial is to test a new drug called selumetinib in combination with another drug called dexamethasone. The trial specifically targets those patients who have relapsed or refractory acute lymphoblastic leukaemia (ALL) and who have an identified mutation in a particular gene in their cancer's DNA (in the RAS pathway). The trialists would like to see what effect combining these two drugs has on the patient's leukaemia. This will include looking at how well this treatment works, finding out more information about how it affects the disease, and to see how safe the drugs are in participants taking the trial medication.

During Phase I the trial will look at establishing what is the most suitable dose level of selumetinib in combination with dexamethasone that can be safely given to participants. The Phase II part of the trial will look at the dose level of selumetinib which has already been established in Phase I as being the most effective in combination with dexamethasone to see what effects the combination of these medications will have on participants' leukaemia.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Yorkshire & The Humber - Leeds West Research Ethics Committee, 12/07/2017, ref: 17/YH/0123

### Study design

Non-randomized; Interventional; Design type: Treatment, Screening, Drug

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

## Acute lymphoblastic leukaemia

### Interventions

Current intervention as of 15/11/2019:

Patients will receive selumetinib on cycle 1 day 1, then continuously from cycle 1 day 4 onwards. Combined with pulsed doses of dexamethasone on days 2-4, 8-11, 15-18 and 22-25 during cycle 1, then on days 1-4 of cycle two, then on days 1-5 during subsequent cycles. Dose levels will be determined throughout phase I using a statistical model, observation of dose limiting toxicities, and pharmacokinetic analysis. Phase II patients will be administered the recommended phase II dose determined from the phase I part of the trial using the same schedule. The aim is to recruit patients to both phases into both arms of the trial over a 2-year period. It is anticipated that patients will be on treatment for approximately 6 months and will be followed up for a further month after completion of treatment.

Previous intervention:

Patients will receive selumetinib on cycle 1 day 1, then continuously from cycle 1 day 4 onwards, combined with dexamethasone from days 2-28 during cycle 1, then tapered dosing for the first week of cycle two, with full doses on days 1-5 during subsequent cycles. Dose levels will be determined throughout phase I using a statistical model, observation of dose limiting toxicities, and pharmacokinetic analysis. Phase II patients will be administered the recommended phase II dose determined from the phase I part of the trial using the same schedule. The aim is to recruit patients to both phases into both arms of the trial over a two-year period. It is anticipated that patients will be on treatment for approximately six months and will be followed up for a further month after completion of treatment.

### Intervention Type

Drug

### Phase

Phase I/II

### Drug/device/biological/vaccine name(s)

Selumetinib

### Primary outcome(s)

Phase I:

Selection of the Recommended Phase II Dose using occurrence/non-occurrence of dose-limiting toxicities and pharmacokinetic results during cycle 1 day 1-28

Phase II:

Response to treatment is measured using morphological response and for patients with CNS involvement only clearance of CSF blasts at cycle 1 day 28

### Key secondary outcome(s)

Phase I:

1. The occurrence of adverse events (AEs) is measured using Common Terminology Criteria for Adverse Events (CTCAE) version 4 and causality assessment from cycle 1 day 1 until 28-day follow-up

2. Pharmacokinetic variables of selumetinib in combination with dexamethasone are measured using the concentration time profile (area under the curve (AUC), C<sub>max</sub>, T<sub>max</sub>, t<sub>1/2</sub>) at cycle 1 day 1, cycle 1 day 4 and cycle 2 day 1

3. Response to treatment is measured by complete remission rate using morphological and minimal residual disease (MRD) response in bone marrow (BM) and for patients with CNS involvement only clearance of Cerebrospinal Fluid (CSF) blasts at cycle 1 day 28
4. Difference in pharmacokinetics of selumetinib measured by the area under the curve (AUC) when selumetinib is administered as a single agent and in combination with dexamethasone at cycle 1 day 1, cycle 1 day 4 and cycle 2 day 1

#### Phase II:

1. The occurrence of adverse events (AEs) measured using Common Terminology Criteria for Adverse Events (CTCAE) version 4 and causality assessment from cycle 1 day 1 until 28-day follow-up
2. The occurrence/non-occurrence of DLTs measured by assessment of the DLTs defined in the trial protocol during cycle 1 day 1-28
3. Pharmacokinetic variables of selumetinib in combination with dexamethasone measured using the concentration time profile (area under the curve (AUC), C<sub>max</sub>, T<sub>max</sub>, t<sub>1/2</sub>) at cycle 1 day 1, cycle 1 day 4 and cycle 2 day 1
4. Difference in pharmacokinetics of selumetinib measured by the area under the curve (AUC) when selumetinib is administered as a single agent and in combination with dexamethasone at cycle 1 day 1, cycle 1 day 4 and cycle 2 day 1
5. MRD response in BM is measured using the MRD level at cycle 1 day 28

#### Completion date

01/08/2023

## Eligibility

#### Key inclusion criteria

Current inclusion criteria as of 23/12/2021:

1. Morphologically proven relapsed/refractory (M2 or M3 marrow; ≥1st relapse for adults, ≥2nd relapse in paediatric group) or progressive B cell precursor or T-Acute Lymphoblastic Leukaemia (ALL) with demonstrated RAS pathway activating mutations (NRAS, KRAS, FLT3, PTPN11, cCBL, NF1, BRAF, IKZF2, IKZF3, IL7Rα or JAK1) identified during the trial screening process
2. B cell precursor patients must either:
  - 2.1 Have received CAR-T cell therapy, or
  - 2.2. Be awaiting CAR-T cell therapy, or
  - 2.3. Be considered ineligible for CAR-T cell therapy
3. Group P (paediatric): <18 years of age; Group A (adult): ≥18 years of age
4. Adequate renal function:
  - 4.1. Group A: Serum creatinine <1.5 x upper limit of normal (ULN)
  - 4.2. Group P as follows:
    - 4.2.1. ≤5 years: Serum creatinine <0.8 mg/dL or 70 µmol/L
    - 4.2.2. >5 years but ≤ 10 years: Serum creatinine <1 mg/dL or 88 µmol/L
    - 4.2.3. >10 years but ≤ 15 years: Serum creatinine <1.2 mg/dL or 106 µmol/L
    - 4.2.4. >15 years: Serum creatinine <1.5 mg/dL or 132 µmol/L
5. Patient is able to swallow selumetinib capsules whole
6. Performance status (PS): Group A - Eastern Cooperative Oncology Group (ECOG) ≤2; Group P - Lansky play scale ≥60% or Karnofsky scale ≥60%
7. Women of childbearing potential must have a negative pregnancy test
8. Patients who are women of childbearing potential and male patients with partners who are women of childbearing potential must agree to use appropriate contraception whilst on trial

9. Written informed consent

10. Absence of any psychological, familial, sociological or geographical factors potentially hampering compliance with the trial protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial

11. Patients who relapse or progress after HSCT need to be at least at day +100, with no signs of Graft versus Host Disease and off immunosuppressive therapy for at least one week

12. Patients who relapse or progress after CAR T cell therapy should be at least 4 weeks after infusion of CAR T cells.

13. Patients must have a body surface area (BSA)  $\geq 0.55 \text{ m}^2$

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Previous inclusion criteria:

1. Morphologically proven relapsed/refractory (M2 or M3 marrow;  $\geq 1$ st relapse for adults,  $\geq 2$ nd relapse in paediatric group) or progressive B cell precursor or T-Acute Lymphoblastic Leukaemia (ALL) with demonstrated RAS pathway activating mutations (NRAS, KRAS, FLT3, PTPN11, cCBL) identified during the trial screening process

2. Group P (paediatric):  $< 18$  years of age; Group A (adult):  $\geq 18$  years of age

3. Adequate renal function:

3.1. Group A: Serum creatinine  $< 1.5 \times$  upper limit of normal (ULN)

3.2. Group P as follows:

3.2.1.  $\leq 5$  years: Serum creatinine  $< 0.8 \text{ mg/dL}$  or  $70 \text{ }\mu\text{mol/L}$

3.2.2.  $> 5$  years but  $\leq 10$  years: Serum creatinine  $< 1 \text{ mg/dL}$  or  $88 \text{ }\mu\text{mol/L}$

3.2.3.  $> 10$  years but  $\leq 15$  years: Serum creatinine  $< 1.2 \text{ mg/dL}$  or  $106 \text{ }\mu\text{mol/L}$

3.2.4.  $> 15$  years: Serum creatinine  $< 1.5 \text{ mg/dL}$  or  $132 \text{ }\mu\text{mol/L}$

4. Patient is able to swallow selumetinib capsules whole

5. Performance status (PS): Group A - Eastern Cooperative Oncology Group (ECOG)  $\leq 2$  (Appendix 6); Group P - Lansky play scale  $\geq 60\%$  or Karnofsky scale  $\geq 60\%$

6. Women of childbearing potential must have a negative pregnancy test

7. Patients who are women of childbearing potential and male patients with partners who are women of childbearing potential must agree to use appropriate contraception whilst on trial

8. Written informed consent

9. Absence of any psychological, familial, sociological or geographical factors potentially hampering compliance with the trial protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial

10. Patients who relapse or progress after HSCT need to be at least at day +100, with no signs of Graft versus Host Disease and off immunosuppressive therapy for at least one week

11. Patients who relapse or progress after CAR T cell therapy should be at least 4 weeks after infusion of CAR T cells.

12. Patients must have a body surface area (BSA)  $\geq 0.55 \text{ m}^2$

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

## Lower age limit

18 years

## Upper age limit

100 years

## Sex

All

## Total final enrolment

12

## Key exclusion criteria

Current exclusion criteria as of 23/12/2021:

1. ALL without presence of RAS-pathway activating mutations
2. Mature B-cell leukaemia and Philadelphia positive ALL
3. Prior exposure to MEK, RAS or RAF inhibitors
4. Any unresolved toxicity  $\geq$  CTCAE Grade 2 from previous anti-cancer therapy, except for alopecia
5. Cardiac conditions as follows:
  - Group A and P
  - 5.1. Prior or current cardiomyopathy including but not limited to the following:
    - 5.1.1. Known hypertrophic cardiomyopathy
    - 5.1.2. Known arrhythmogenic right ventricular cardiomyopathy
  - 5.2. Even if full recovery has occurred, previous moderate or severe impairment of left ventricular systolic function (LVEF  $<$  45% on ECHO in Group A; SF  $<$  29% in Group P but excluding transient impairments due to e.g. anaemia/sepsis or results not thought to represent a true reflection of cardiac function)
  - 5.3. Severe valvular heart disease
  - 5.4. Severe congenital heart disease
  - 5.5. Uncontrolled hypertension:
    - Group A: BP  $\geq$  150/95 mmHg despite medical therapy;
    - Group P: BP  $\geq$  95th percentile for age, height and gender (please refer to Blood Pressure by Age and Height Percentiles tables)
  - Group A
  - 5.6. Baseline (LVEF) below the lower limit of normal (LLN) or  $<$  55% measured by ECHO
  - 5.7. Acute coronary syndrome within 6 months prior to trial registration
  - 5.8. Uncontrolled Angina - Canadian Cardiovascular Society grade II-IV despite medical therapy
  - 5.9. Symptomatic heart failure New York Heart Association (NYHA) Class II-IV, prior or current cardiomyopathy, or severe valvular heart disease
  - 5.10. Prior or current cardiomyopathy including but not limited to the following:
    - 5.10.1. Known hypertrophic cardiomyopathy
    - 5.10.2. Known arrhythmogenic right ventricular cardiomyopathy
  - 5.11. Atrial fibrillation with a ventricular rate  $>$  100 bpm on Electrocardiogram (ECG) at rest
  - 5.12. QTcF  $>$  450ms in male patients or  $\geq$  460ms in female patients, or other factors that increase the risk of QT prolongation
  - Group P
  - 5.13. Baseline SF  $<$  29%
  - 5.14. Atrial fibrillation with a ventricular rate  $>$  130 bpm on Electrocardiogram (ECG) at rest
  - 5.15. QTcF  $>$  450ms in patients  $<$  12 years or  $\geq$  460ms in patients  $\geq$  12 but  $<$  18 years

6. Ophthalmological conditions as follows:

6.1. Current or past history of retinal pigment epithelial detachment (RPED)/central serous retinopathy (CSR) or retinal vein occlusion (RVO)

6.2. Intraocular pressure (IOP) > 21 mmHg or uncontrolled glaucoma (irrespective of IOP)

7. Pregnant and breast feeding females

8. Known severe hypersensitivity to selumetinib, dexamethasone or combination medications or any excipient of these medicinal products, or history of allergic reactions attributed to compounds of similar chemical or biologic composition to selumetinib

9. Have received or are receiving an IMP or other systemic anti-cancer treatment (not including dexamethasone, prednisilone, or hydroxycarbamide) within 4 weeks (6 weeks for nitrosoureas, mitomycin, and suramin) prior to trial registration, or within a period during which the IMP or systemic anticancer treatment has not been cleared from the body (e.g. a period of 5 'half-lives'), whichever is the most appropriate and as judged by the investigator

10. Have had recent major surgery within a minimum 4 weeks prior to trial registration, with the exception of surgical placement of vascular access

11. Have received radiation therapy within 4 weeks prior to trial registration, or limited field of radiation for palliation within 7 days of the first dose of trial treatment

12. Laboratory values as listed below (SI units):

12.1. Serum bilirubin > 1.5 x ULN (unless due to Gilbert's syndrome)

13. Have evidence of any other significant clinical disorder or laboratory finding that, as judged by the investigator, makes it undesirable for the patient to participate in the trial

14. Have any evidence of a severe or uncontrolled systemic disease (e.g. unstable or uncompensated respiratory, cardiac, hepatic, or renal disease, active infection (including hepatitis B, hepatitis C, HIV), active bleeding diatheses, or renal transplant)

15. Have refractory nausea and vomiting, chronic gastrointestinal diseases (e.g., inflammatory bowel disease), or significant bowel resection that would adversely affect the absorption /bioavailability of the orally administered trial medication

16. Any other active malignancy which, in the opinion of the investigator would limit the ability of the patient to complete the study

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Previous exclusion criteria:

1. ALL without presence of RAS-pathway activating mutations

2. Mature B-cell leukaemia and Philadelphia positive ALL

3. Prior exposure to MEK, RAS or RAF inhibitors

4. Any unresolved toxicity > = CTCAE Grade 2 from previous anti-cancer therapy, except for alopecia

5. Cardiac conditions as follows:

Group A and P

5.1. Prior or current cardiomyopathy including but not limited to the following:

5.1.1. Known hypertrophic cardiomyopathy

5.1.2. Known arrhythmogenic right ventricular cardiomyopathy

5.2. Even if full recovery has occurred, previous moderate or severe impairment of left ventricular systolic function (LVEF < 45% on ECHO in Group A; SF < 29% in Group P but excluding transient impairments due to e.g. anaemia/sepsis or results not thought to represent a true reflection of cardiac function)

5.3. Severe valvular heart disease

5.4. Severe congenital heart disease

5.5. Uncontrolled hypertension:

Group A: BP > = 150/95 mmHg despite medical therapy;

Group P: BP  $\geq$  95th percentile for age, height and gender (please refer to Blood Pressure by Age and Height Percentiles tables)

Group A

- 5.6. Baseline (LVEF) below the lower limit of normal (LLN) or  $<$  55% measured by ECHO
- 5.7. Acute coronary syndrome within 6 months prior to trial registration
- 5.8. Uncontrolled Angina - Canadian Cardiovascular Society grade II-IV despite medical therapy
- 5.9. Symptomatic heart failure New York Heart Association (NYHA) Class II-IV, prior or current cardiomyopathy, or severe valvular heart disease
- 5.10. Prior or current cardiomyopathy including but not limited to the following:
  - 5.10.1. Known hypertrophic cardiomyopathy
  - 5.10.2. Known arrhythmogenic right ventricular cardiomyopathy
- 5.11. Atrial fibrillation with a ventricular rate  $>$  100 bpm on Electrocardiogram (ECG) at rest
- 5.12. QTcF  $>$  450ms in male patients or  $\geq$  460ms in female patients, or other factors that increase the risk of QT prolongation

Group P

- 5.13. Baseline SF  $<$  29%
- 5.14. Atrial fibrillation with a ventricular rate  $>$  130 bpm on Electrocardiogram (ECG) at rest
- 5.15. QTcF  $>$  450ms in patients  $<$  12 years or  $\geq$  460ms in patients  $\geq$  12 but  $<$  18 years
- 6. Ophthalmological conditions as follows:
  - 6.1. Current or past history of retinal pigment epithelial detachment (RPED)/central serous retinopathy (CSR) or retinal vein occlusion
  - 6.2. Intraocular pressure (IOP)  $>$  21 mmHg or uncontrolled glaucoma (irrespective of IOP)
- 7. Pregnant and breast feeding females
- 8. Known severe hypersensitivity to selumetinib, dexamethasone or combination medications or any excipient of these medicinal products, or history of allergic reactions attributed to compounds of similar chemical or biologic composition to selumetinib
- 9. Have received or are receiving an IMP or other systemic anti-cancer treatment (not including dexamethasone or hydroxycarbamide) within 4 weeks (6 weeks for nitrosoureas, mitomycin, and suramin) prior to trial registration, or within a period during which the IMP or systemic anticancer treatment has not been cleared from the body (e.g. a period of 5 'half-lives'), whichever is the most appropriate and as judged by the investigator
- 10. Have had recent major surgery within a minimum 4 weeks prior to trial registration, with the exception of surgical placement of vascular access
- 11. Have received radiation therapy within 4 weeks prior to trial registration, or limited field of radiation for palliation within 7 days of the first dose of trial treatment
- 12. Laboratory values as listed below (SI units):
  - 12.1. Serum bilirubin  $>$  1.5 x ULN (unless due to Gilbert's syndrome)
- 13. Have evidence of any other significant clinical disorder or laboratory finding that, as judged by the investigator, makes it undesirable for the patient to participate in the trial
- 14. Have any evidence of a severe or uncontrolled systemic disease (e.g. unstable or uncompensated respiratory, cardiac, hepatic, or renal disease, active infection (including hepatitis B, hepatitis C, HIV), active bleeding diatheses, or renal transplant)
- 15. Have refractory nausea and vomiting, chronic gastrointestinal diseases (e.g., inflammatory bowel disease), or significant bowel resection that would adversely affect the absorption /bioavailability of the orally administered trial medication
- 16. Any other active malignancy which, in the opinion of the investigator would limit the ability of the patient to complete the study

**Date of first enrolment**

18/05/2018

**Date of final enrolment**

31/01/2023

**Locations****Countries of recruitment**

United Kingdom

England

Scotland

Denmark

Netherlands

**Study participating centre****Freeman Hospital**

Freeman Rd

High Heaton

Newcastle upon Tyne

England

NE7 7DN

**Study participating centre****Great North Children's Hospital**

Royal Victoria Infirmary

Queen Victoria Rd

Newcastle upon Tyne

England

NE1 4LP

**Study participating centre****Birmingham Children's Hospital**

Steelhouse Ln

Birmingham

England

B4 6NH

**Study participating centre****Queen Elizabeth Hospital Birmingham**

Mindelsohn Way

Birmingham

England  
B15 2TH

**Study participating centre**  
**Alder Hey Children's Hospital Liverpool**  
East Prescott Road  
Liverpool  
England  
L14 5AB

**Study participating centre**  
**Royal Marsden Hospital**  
Downs Rd  
Sutton  
England  
SM2 5PT

**Study participating centre**  
**University College London Hospital**  
Gower St  
Bloomsbury  
London  
England  
WC1E 6BT

**Study participating centre**  
**Christie Hospital**  
Wilmslow Rd  
Manchester  
England  
M20 4BX

**Study participating centre**  
**Royal Hallamshire Hospital**  
Glossop Rd  
Sheffield  
England  
S10 2JF

**Study participating centre**  
**Great Ormond Street Hospital**  
Great Ormond Street  
Holborn  
London  
England  
WC1N 3JH

**Study participating centre**  
**Hammersmith Hospital**  
Du Cane Rd  
White City  
London  
England  
W12 0HS

**Study participating centre**  
**King's College Hospital**  
Denmark Hill  
Camberwell  
London  
England  
SE5 9RS

**Study participating centre**  
**Beatson West of Scotland Cancer Centre**  
1053 Great Western Road  
Glasgow  
Scotland  
G12 0YN

**Study participating centre**  
**Prinses Máxima Centrum**  
Heidelberglaan 25  
Utrecht  
Netherlands  
3584 CS

**Study participating centre**  
**University Hospital Rigshospitalet**  
Blegdamsvej 9

Copenhagen  
Denmark  
DK-2100

## Sponsor information

### Organisation

University of Birmingham

### ROR

<https://ror.org/03angcq70>

## Funder(s)

### Funder type

Industry

### Funder Name

AstraZeneca

### Alternative Name(s)

AstraZeneca PLC, Pearl Therapeutics, AZ

### Funding Body Type

Government organisation

### Funding Body Subtype

For-profit companies (industry)

### Location

United Kingdom

### Funder Name

Cancer Research UK; Grant Codes: C27943/A22304

### Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

Current individual participant data (IPD) sharing statement as of 27/01/2022:

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. The CRCTU is committed to responsible and controlled sharing of anonymised clinical trial data with the wider research community to maximise potential patient benefit while protecting the privacy and confidentiality of trial participants. Data anonymised in compliance with the Information Commissioners Office requirements, using a procedure based on guidelines from the MRC Methodology Hubs, will be available for sharing with researchers outside of the trials team within 6 months of the primary publication. More detailed information on the CRCTU's Data Sharing Policy and the mechanism for obtaining data can be found on the CRCTU website: <https://www.birmingham.ac.uk/research/activity/mds/trials/crctu/index.aspx>.

Previous individual participant data (IPD) sharing statement:

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository (<https://www.cancertrials.bham.ac.uk/SeluDexLive>). Type of data that will be shared: case report form data. When the data will become available and for how long: from trial entry registration until the end of the trial. Access to the eRDC system will be granted to authorised individuals via the UK Coordinating Centre, for analysis of outcome measures, Phase I dose escalation continual reassessment method, Phase II Bayesian design. Consent from participants was obtained prior to trial entry,

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		12/02/2026	17/02/2026	Yes	No
<a href="#">Protocol article</a>		04/03/2022	07/03/2022	Yes	No
<a href="#">Basic results</a>	version 1.0	17/04/2025	28/04/2025	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Statistical Analysis Plan</a>	version 2.0	09/09/2019	28/04/2025	No	No
<a href="#">Study website</a>		11/11/2025	11/11/2025	No	Yes