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STOMP: Small cell lung cancer Trial of Olaparib (AZD2281) as Maintenance Programme

Submission date 03/08/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/09/2010	**Overall study status** Completed	
Last Edited 07/10/2024	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-olaparib-small-cell-lung-cancer-stomp

Study website
https://www.birmingham.ac.uk/research/activity/mds/trials/crctu/trials/stomp/index.aspx

Contact information

Type(s)
Scientific

Contact name
Prof Penella Woll

Contact details
University of Sheffield
Weston Park Hospital
Whitham Road
Sheffield
United Kingdom
S10 2SJ

Additional identifiers

EudraCT/CTIS number
2010-021165-76

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LU2006

Study information

Scientific Title
Small cell lung cancer Trial of Olaparib (AZD2281) as Maintenance Programme: a randomised, double blind, multicentre phase II trial

Acronym
STOMP

Study objectives
The use of olaparib as a maintenance therapy in patients with chemoresponsive small cell lung cancer (SCLC) prolongs the period of progression-free survival beyond that of using a placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 08/10/2013: York and Humber - Leeds East, 31/08/2011, ref: 11/YH/0290

Study design
Multicentre double-blind randomized placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Small cell lung cancer

Interventions
Patients will be randomised to receive either olaparib or placebo 200 mg orally (per os [po]) twice a day (bis in die [bd]) for up to 2 years.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Olaparib (AZD2281)

Primary outcome measure
Current primary outcome as of 23/01/2019:
Progression-free survival time

Previous primary outcome:
Progression-free survival rate at 4 months from randomisation

Secondary outcome measures
Current secondary outcomes as of 23/01/2019:
1. Progression-free survival rate at 4 months from randomisation
2. Overall survival time
3. Overall survival rate at 6 months
4. Changes in performance status
5. Quality of life
6. Adverse events
7. Biomarkers: blood and biopsy samples will be collected for analysis of PARP and DNA repair pathways

Previous secondary outcomes:
1. Progression-free survival time
2. Overall survival time
3. Overall survival rate at 6 months
4. Changes in performance status
5. Quality of life
6. Adverse events
7. Biomarkers: blood and biopsy samples will be collected for analysis of PARP and DNA repair pathways

Overall study start date
06/01/2011

Completion date
19/09/2015

Eligibility

Key inclusion criteria
Current inclusion criteria as of 23/01/2019:
1. Pathologically confirmed SCLC (limited or extensive stage)
2. Completed at least 3 cycles of first-line chemotherapy or chemo-radiotherapy with cisplatin + etoposide or carboplatin + etoposide
3. Complete Response (CR) or Partial Response (PR) to first-line chemotherapy (RECIST criteria)
4. ECOG performance status 0-2
5. Resolution of all treatment toxicity to grade 1 or better

6. Adequate physiological function:
6.1. Renal:
6.1.1. Calculated or measured creatinine clearance ≥50 ml/min
6.1.2. Serum creatinine ≤1.5 x institutional upper limit of normal (ULN)
6.2. Haematological:
6.2.1. Haemoglobin ≥9.0 g/dL
6.2.2. White blood cells (WBC) ≥3x109/L
6.2.3. Absolute Neutrophil Count (ANC) ≥1.5 x 109/L
6.2.4. Platelet count ≥ 100 x 109/L
6.2.5. International Normalized Ratio (INR) ≤1.2
6.3. Hepatic:
6.3.1. Aspartate Aminotransferase (AST)/Alanine Aminotransferase (ALT) ≤2.5 x institutional ULN unless liver metastases are present in which case it must be ≤5x ULN
6.3.2. Bilirubin within normal range
7. Negative pregnancy test and agrees to comply with contraceptive measures
8. Provision of written informed consent
9. Able to swallow oral medication
10. Patient is willing and able to comply with the protocol for the duration of the study including undergoing treatment and scheduled visits and examinations

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6.2.2. White blood cells (WBC) ≥3 x 10e9/L
6.2.3. Absolute Neutrophil Count (ANC) ≥ 1.5 x 10e9/L
6.2.4. Platelet count ≥100 x 109/L
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Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
128

Total final enrolment
220

Key exclusion criteria
Current exclusion criteria as of 23/01/2019:
1. Age ≤18 years
2. Interval from last anticancer treatment to the start of the study treatment:
2.1. Radiotherapy ≥21 days
2.2. Chemotherapy ≥42 days
3. Symptomatic brain metastases
4. Interstitial lung disease
5. Previous malignancies (except curatively treated non-melanoma skin cancer or carcinoma in situ of the cervix or breast) within the past 3 years
6. History of malabsorption or major gastrointestinal tract resection likely to affect study drug absorption.
7. Treatment with any investigational product during the last 14 days (or a longer period depending on the defined characteristics of the agents used)
8. Any previous treatment with a PARP inhibitor, including olaparib
9. Patients receiving the following classes of inhibitors of CYP3A4; azole antifungals; macrolide antibiotics; protease inhibitors
10. Patients considered a poor medical risk due to a serious, uncontrolled medical disorder, non-malignant systemic disease or active, uncontrolled infection. Examples include, but are not limited to, uncontrolled ventricular arrhythmia, recent (within 3 months) myocardial infarction, uncontrolled major seizure disorder, unstable spinal cord compression, superior vena cava syndrome, or any psychiatric disorder that prohibits obtaining informed consent.
11. Breastfeeding women
12. Immunocompromised patients, e.g., patients who are known to be serologically positive for human immunodeficiency virus (HIV)
13. Patients with known active hepatic disease (i.e., Hepatitis B or C)
14. Patients with a known hypersensitivity to Olaparib or any of the excipients of the product
15. Patients with uncontrolled seizures
16. Patients with myelodysplastic syndrome (MDS) / acute myeloid leukaemia (AML)
17. Major surgery within 14 days of starting trial treatment and patients must have recovered from any effects of any major surgery

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1. Age ≤18 years
2. Interval from last anticancer treatment to the start of the study treatment:
2.1. Radiotherapy ≥21 days
2.2. Chemotherapy ≥42 days
3. Symptomatic brain metastases
4. Active infection on the day of enrollment
5. Interstitial lung disease
6. Previous malignancies (except curatively treated non-melanoma skin cancer or carcinoma in situ of the cervix or breast) within the past 3 years

7. History of malabsorption or major gastrointestinal tract resection likely to affect study drug absorption.
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Date of first enrolment
06/01/2011

Date of final enrolment
19/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sheffield
Sheffield
United Kingdom
S10 2SJ

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

Sponsor details
Research Department
11 Broomfield Lane

Sheffield
England
United Kingdom
S10 2SE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Research council

Funder Name
Clinical Trials Advisory and Awards Committee (CTAAC) (UK)

Funder Name
AstraZeneca (UK)

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	abstract	01/01/2017	23/01/2019	No	No
Basic results	version 1.0	08/12/2021	20/12/2021	No	No
Results article		15/07/2022	26/07/2022	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			07/10/2024	No	Yes