ISRCTN73164486 https://doi.org/10.1186/ISRCTN73164486

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

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

Clinical Trials Information System (CTIS)
2010-021165-76

Protocol serial number
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

Primary study design
Interventional

Study design
Multicentre double-blind randomized placebo-controlled trial

Study type(s)
Treatment

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(s)
Current primary outcome as of 23/01/2019:
Progression-free survival time

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

Key secondary outcome(s)

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

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

Previous inclusion criteria:
1. Pathologically confirmed SCLC (limited or extensive stage)
2. Completed at least 3 cycles of first-line chemotherapy with cisplatin or carbopatin + 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) ≥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
6.2.5. International Normalized Ratio (INR) ≤1.2
6.3. Hepatic:
6.3.1. Aspartate Aminoransferase (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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

Previous exclusion criteria:
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.
8. Treatment with any investigational product during the last 14 days (or a longer period depending on the defined characteristics of the agents used)
9. Any previous treatment with a PARP inhibitor, including olaparib
10. Patients receiving the following classes of inhibitors of CYP3A4; azole antifungals; macrolide antibiotics; protease inhibitors
11. 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.
12. Breastfeeding women
13. Immunocompromised patients, e.g., patients who are known to be serologically positive for human immunodeficiency virus (HIV)
14. Patients with known active hepatic disease (i.e., Hepatitis B or C)

15. Patients with a known hypersensitivity to Olaparib or any of the excipients of the product
16. Patients with uncontrolled seizures

Date of first enrolment
06/01/2011

Date of final enrolment
19/09/2015

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

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, AZ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

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

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/07/2022	26/07/2022	Yes	No
Abstract results	abstract	01/01/2017	23/01/2019	No	No
Basic results	version 1.0	08/12/2021	20/12/2021	No	No
HRA research summary			28/06/2023	No	No
Plain English results			07/10/2024	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes