ISRCTN42408038 https://doi.org/10.1186/ISRCTN42408038

Can cytology replace tumor tissue in determining somatic mutations of BRCA 1/2 genes in patients with epithelial carcinoma of ovaries, fallopian tubes or peritoneal serous carcinoma?

Submission date	Recruitment status	[_] Prospectively registered
19/11/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/11/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/08/2024	Cancer	

Plain English summary of protocol

Background and study aims

In patients with high grade serous epithelial cancer (i.e. involving cancer cells lining a cavity that contains fluid – such as the abdominal cavity - that look very abnormal and growing aggressively) of the ovaries, fallopian tubes or serous peritoneal (lining of the abdomen) cancer the risk of BRCA 1/2 gene mutations is up to 22%. Mutations of BRCA 1/2 genes can be either germline (inherited) or somatic (mutations caused by, for example, exposure to chemicals). Recently, a new targeted drug called olaparib has been approved for treatment of relapsed (cancer that, having gone into remission after treatment has come back) high-grade serous cancer of the ovaries, fallopian tubes or peritoneum in patients with known BRCA 1/2 gene mutations (either germline or somatic).

At the moment the testing for BRCA 1/2 gene mutations is provided from blood sample analysis (after prior genetic counselling) providing information about germline mutations only. For somatic mutations of BRCA 1/2 genes, samples of tumor tissue (paraffin-embeded samples) are recommended. However, it is known that paraffin causes difficulties in determining genetic mutations from tumor tissues. The aim of this study is to determine if cytology material (body cells) obtained from malignant ascites (fluid build-up resulting from cancer) provides the same quality of tumor DNA than material obtained from tumor tissue for detection of BRCA 1/2 somatic gene mutations in patients with high-grade serous epithelial carcinoma of ovaries, fallopian tubes or serous peritoneal carcinoma.

Who can participate?

Women with malignant ascites caused by high-grade serous epithelial carcinoma of the ovaries, fallopian tubes or serous peritoneal carcinoma (cancer of the lining of the abdomen).

What does the study involve?

Participants are asked to give blood, tumor tissue (paraffin-embeded) and ascites (fluid)

samples. These samples are then analysed for BRCA 1/2 gene mutations. From ascites and tumor tissue information about somatic BRCA 1/2 gene mutations are provided, whereas from blood sample information about germline mutations of BRCA 1/2 gene mutations are provided.

What are the possible benefits and risks of participating?
None - no influence on standard treatment.

Where is the study run from?
Institute of Oncology Ljubljana (Slovenia)

When is the study starting and how long is it expected to run for?
From October 2015 to December 2017

Who is funding the study?
1. Institute of Oncology Ljubljana (Slovenia)
2. AstraZeneca UK

Who is the main contact?
Dr. Erik Škof

Contact information

Type(s)
Scientific

Contact name
Dr Erik Skof

Contact details
Department for Medical Oncology
Institute of Oncology Ljubljana
Zaloska 2
Ljubljana
Slovenia
1000

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Can cytology replace tumor tissue in determining somatic mutations of BRCA 1/2 genes in patients with epithelial carcinoma of ovaries, fallopian tubes or peritoneal serous carcinoma? A single-centre diagnostic trial

Study objectives
Cytology material obtained from malignant ascites provides the same quality of tumor DNA than material obtained from tumor tissue for detection of BRCA 1/2 somatic gene mutations in patients with epithelial carcinoma of ovaries, fallopian tubes or serous peritoneal carcinoma

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Republic of Slovenia Commission for Medical Ethics (Komisija Republike Slovenije za Medicinsko Etiko), 27/ 07/ 2015, ref: KME 100/05/15
2. Republic of Slovenia National Medical Ethics Committee, 27/07/2015, ref: NMEC 100/05/15

Study design
Single-centre diagnostic trial

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Malignant ascites in patients with high grade serous cancer of ovaries, fallopian tubes or peritoneal serous cancer

Interventions
In each eligible patient, testing for somatic BRCA 1/2 gene mutations will be provided from malignant ascites and tumor tissue (paraffin block) and testing for germline BRCA 1/2 gene mutations from a blood sample.

Intervention Type
Genetic

Primary outcome measure
Determination of somatic BRCA 1/2 gene mutations from cytology material provided from malignant ascites and tumor tissue - 100% correlation expected, proper method to be identified.

Secondary outcome measures

N/A

Overall study start date
01/02/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Malignant ascites determined by cytology
2. Histology proven high-grade serous cancer of ovaries, fallopian tubes or serous peritoneal cancer

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
40

Key exclusion criteria
1. Non-malignant ascites
2. Histology other than high-grade serous cancer of ovaries, fallopian tubes or serous peritoneal cancer

Date of first enrolment
01/10/2015

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Slovakia

Slovenia

Study participating centre
Institute Of Oncology Ljubljana
Zaloska 2

Ljubljana
Slovenia
1000

Sponsor information

Organisation
Institute of Oncology Ljubljana

Sponsor details
Zaloska 2
Ljubljana
Slovenia
1000

Sponsor type
Hospital/treatment centre

Website
www.onko-i.si

ROR
https://ror.org/00y5zsg21

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Institute Of Oncology Ljubljana (Slovenia)

Funder Name
AstraZeneca

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
Annual ASCO or ESMO meeting – preliminary results in 2017
Scientific paper with significant SCI after end of trial

Intention to publish date
01/06/2018

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?
Results article	results	02/04/2019		Yes	No
Other publications		10/03/2022	03/01/2023	Yes	No
Results article		22/08/2024	27/08/2024	Yes	No