







# 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?

<b>Submission date</b> 19/11/2015	<b>Recruitment status</b> No longer recruiting	 Retrospectively registered
		 Protocol not yet added
<b>Registration date</b> 24/11/2015	<b>Overall study status</b> Completed	 SAP not yet added
		 Results added
<b>Last Edited</b> 03/01/2023	<b>Condition category</b> Cancer	 Raw data not yet added
		 Study completed

## Plain English Summary

### 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-embedded 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-embedded) 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**

**Protocol/serial number**

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 hypothesis**

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**

## **Condition**

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

**Overall study end date**

31/12/2017

## Eligibility

**Participant 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

**Participant exclusion criteria**

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

**Recruitment start date**

01/10/2015

**Recruitment end date**

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](http://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?
<a href="#">Results article</a>	results	02/04/2019		Yes	No
<a href="#">Other publications</a>		10/03/2022	03/01/2023	Yes	No