

Study to measure how well aspirin is able to reduce the number of platelets in the blood of patients with reactive thrombocytosis caused by pseudomyxoma peritonei (a rare form of cancer that affects the lining of the abdomen and pelvis)

Submission date 16/01/2023	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/02/2023	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/03/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Pseudomyxoma peritonei (PMP) is a rare form of cancer that affects the lining of the abdomen and pelvis. In some cases, people with PMP may develop reactive thrombocytosis, which can be caused by the cancer itself or as a response to treatment. This can increase the risk of blood clots and other complications.

Patients who have surgery for pseudomyxoma peritonei can sometimes have high platelet counts after the operation. Platelets are a type of blood cell in the body that is involved in the blood clotting process. High platelet counts can sometimes cause abnormal blood clots to form so they are prescribed aspirin which blocks platelets. Previous research has shown that in some patients aspirin does not block platelets and therefore is ineffective. This phenomenon is known as aspirin resistance. In this study we want to identify those patients who are aspirin resistant.

Who can participate?

Patients undergoing surgery for pseudomyxoma peritonei and who develop high platelet counts after surgery are eligible to take part in the study.

What does the study involve?

The study involves taking blood samples before patients are administered aspirin and at different time points after they take aspirin.

What are the possible benefits and risks of participating?

It is beneficial to know if patients are aspirin resistant as it means the drug is not effectively working. The risks are minimal and only involve slight discomfort during venepuncture.

Where is the study run from?
Hampshire Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2021 to June 2025

Who is funding the study?
1. Pelican Cancer Foundation (UK)
2. Peritoneal Malignancy Institute (UK)

Who is the main contact?
Dr Sophia Stanford, sophia.stanford@hhft.nhs.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Sophia Stanford

ORCID ID
<https://orcid.org/0000-0002-7855-1991>

Contact details
Peritoneal Malignancy Unit
The Ark Centre
Dinwoodie Drive
Basingstoke
United Kingdom
RG24 9NN
+44 1256319811
sophia.stanford@hhft.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
318927

Protocol serial number
IRAS 318927, CPMS 54712

Study information

Scientific Title
A prospective observational study to measure platelet inhibition by aspirin administered for reactive thrombocytosis in Pseudomyxoma Peritonei patients

Study objectives

The main stay treatment for Pseudomyxoma Peritonei (PMP) is complete cytoreductive surgery (CRS) with Hyperthermic Intraperitoneal Chemotherapy (HIPEC). Following surgery a proportion of these patients develop reactive thrombocytosis and are administered prophylactic dose of aspirin (75mg) for 6 weeks. Previous studies have shown that patients with reactive thrombocytosis are at risk of abnormal thrombosis. Although these patients are administered aspirin because they are at risk of thrombosis we do not know how effectively platelets are being inhibited by aspirin. The phenomenon of aspirin resistance or aspirin treatment failure has been previously described and we currently do not know what proportion of our patients are aspirin resistant i.e. if the aspirin prescribed is effectively inhibiting patients.

This study will measure aspirin inhibition using VerifyNow a point of care test.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 28/11/2022, North of Scotland Research Ethics committee (Summerfield house, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44(0)1224 558458; gram.nosres@nhs.scot), ref: 22/NS/0156

Study design

Prospective observational study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Pseudomyxoma peritonei

Interventions

An observational study using blood samples to measure aspirin resistance in post-operative PMP patients who have reactive thrombocytosis and are prescribed aspirin.

Blood samples will be taken at baseline before administration of aspirin, 4 hours after (day 0), day 1, day 3, Day 5 and day 14 or day of discharge whichever comes first for VerifyNow measurements. In addition, a blood sample will be taken simultaneously at the same time points for full blood count analysis which will provide information on platelet count. At day 60 patients will be contacted via a telephone call to determine if they have had a thrombotic event.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Aspirin

Primary outcome(s)

Aspirin resistance measured at baseline, 4 hours post aspirin administration, day 1, day 3, day 5 and day 14 or day of discharge, which ever comes first using the VerifyNow™.

Key secondary outcome(s)

Determine if there are any thromboembolic events at 60 days post-operatively via completion of a questionnaire.

Completion date

30/06/2025

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility**Key inclusion criteria**

1. Patients >18 years of age
2. Diagnosis of Pseudomyxoma Peritonei
3. Patients undergoing CRS and HIPEC
4. Post-operative platelet count of $>1000 \times 10^9/L$

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

30

Key exclusion criteria

1. Patients <18 years of age
2. Having CRS and HIPEC for other conditions apart from Pseudomyxoma Peritonei
3. Allergic to aspirin
4. On other antiplatelet or drugs that affect platelet function e.g. NSAIDs
5. Ischaemic vascular events, percutaneous coronary intervention, or coronary artery bypass within the last 12 months

Date of first enrolment

16/01/2023

Date of final enrolment

31/12/2024

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Hampshire Hospitals NHS Foundation Trust

Basingstoke and North Hampshire Hos

Aldermaston Road

Basingstoke

United Kingdom

RG24 9NA

Sponsor information

Organisation

Hampshire Hospitals NHS Foundation Trust

ROR

<https://ror.org/04shzs249>

Funder(s)

Funder type

Charity

Funder Name

Pelican Cancer Foundation

Alternative Name(s)

Pelicanfon

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Peritoneal Malignancy Institute

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available due to patient confidentiality.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No