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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

Registration date
02/02/2023

Overall study status
Stopped

Last Edited
10/03/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 pseudomyoma 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

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Additional identifiers

Integrated Research Application System (IRAS)
318927

Central Portfolio Management System (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

Primary study design
Observational

Study design
Prospective observational study

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 VerifyNowTM.

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 x 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