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The use of autologous platelet-rich-plasma during surgery in patients with gynecological cancer improves wound healing and reduces postoperative pain feeling

Submission date
22/05/2024

Recruitment status
No longer recruiting

Registration date
01/07/2024

Overall study status
Completed

Last Edited
05/08/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Oncological patients are at high risk of developing postoperative wound complications, including failure of proper wound healing (wound dehiscence), defined as complete or partial wound separation (>1 cm long). Platelet-rich plasma (PRP) is a concentrate of plasma rich in platelets derived from whole blood, centrifuged to remove red blood cells. It has a higher concentration of growth factors than whole blood and is widely used in regenerative medicine to encourage the healing of bone and soft tissues. The use of PRP may also reduce pain in the postoperative period. This study aims to evaluate the impact of PRP application during surgical treatment on wound healing and pain intensity feeling in patients with gynecological cancers (ovarian, endometrial or cervical cancer).

Who can participate?
Adult patients aged >18 years old diagnosed with gynecological cancers (ovarian, endometrial or cervical cancer) qualified for surgical treatment by laparotomy (a surgical procedure that involves making an incision through the abdominal wall to gain access into the abdominal cavity)

What does the study involve?
The study involves the application of PRP or placebo (saline infusion) into the wound during a surgical procedure. Patients included in the study are unaware of what kind of intervention they receive – PRP or placebo. After surgery, patients are asked to assess pain intensity by fulfilling appropriate questionnaires (immediately after surgery, 6 and 12 hours after surgery). Patients are also asked to come for follow-up visits and fulfill additional questionnaires regarding scar quality and quality of life assessment on days 1, 8, 30 and 90 after surgery.

What are the possible benefits and risks of participating?
The possible benefit of participation in this study is an improvement in wound healing and a reduction in pain intensity after surgery. Platelet-rich plasma or placebo application is performed under anesthesia during the abdominal wall closure, thus it doesn’t cause any

additional pain or discomfort for the patient. The procedure needs blood sample collection, but it can be performed during routine preoperative blood testing. The use of PRP is safe because it is derived from the patient's blood – therefore there is no risk of allergic reactions either during the first or subsequent applications.

Where is the study run from?
The study is run by the Department of Obstetrics, Women's Diseases and Oncogynecology, National Medical Institute of the Ministry of the Interior and Administration in Warsaw, Poland

When is the study starting and how long is it expected to run for?
June 2016 to December 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Tadeusz Issat, tadeusz.issat@imid.med.pl

Contact information

Type(s)
Public, Principal Investigator

Contact name
Prof Tadeusz Issat

ORCID ID
https://orcid.org/0000-0002-3647-3550

Contact details
Kasprzaka 17a
Warszawa
Poland
01-211
+48223277044
tadeusz.issat@imid.med.pl

Type(s)
Public, Scientific

Contact name
Dr Katarzyna Pankiewicz

ORCID ID
https://orcid.org/0000-0001-7756-1963

Contact details
Kasprzaka 17a
Warszawa
Poland
01-211

+48223277044
katarzyna.pankiewicz@imid.med.pl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The application of autologous platelet-rich-plasma during laparotomy in patients with gynecological malignancies improves wound healing and reduces postoperative pain feeling – a single-blind placebo-controlled intervention study (preliminary report)

Study objectives
Platelet-rich plasma (PRP) application into the wound during surgery in gynecological cancer patients improves wound healing and reduces pain in the postoperative period

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/11/2016, The Bioethical Committee of Central Clinical Hospital of Interior in Warsaw (Wolska 137, Warsaw, 02-507, Poland; +48 47 722 15 52; komisja.etyki@cskmswia.gov.pl), ref: 99/2016

Study design
Single-center single-blind placebo-controlled interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Gynecological cancer

Interventions
Adult women undergoing surgical treatment because of female genital tract malignancies are included. Patients are randomly assigned to one of the two different groups: Group 1 will receive an application of platelet-rich plasma (PRP) and Group 2 (control group) will receive an application of placebo (0,9% NaCl solution) into the wound during the surgery. The allocation ratio is 1:1 and it is supervised by an independent clinician, who is not involved in the PRP application during surgery. The randomization is performed manually and the allocation concealment is performed by using sequentially numbered opaque envelopes.

Surgical treatment is performed by laparotomy with the midline incision in all patients. Surgical procedures include bilateral salpino-oophorectomy, total abdominal hysterectomy with bilateral salpingo-oophorectomy, radical hysterectomy with pelvic lymph node assessment and ovarian cancer full protocol. At the end of the surgery, during the abdominal closure, PRP or a placebo (0.,9% NaCl solution) is applied by a series of microinjections into the abdominal muscles fascia, as well as into the subcutaneous tissue. All patients receive antibiotic prophylaxis with a single dose of 2g cefazolin administered intravenously up to 20 minutes before skin incision. All patients have general anesthesia during the procedure. After the surgery, all patients are treated with analgesics. The basic therapy is intravenous paracetamol and morphine administered in the form of patient-controlled analgesia (PCA). Additionally, some patients are treated with intravenous metamizole or ketoprofen, when needed.

Intervention Type
Biological/Vaccine

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Autologous platelet-rich-plasma

Primary outcome measure
Wound dehiscence, defined as both complete and partial wound separation (>1 cm long) diagnosed by the clinician during the follow-up period

Secondary outcome measures
1. Postoperative pain intensity measured using a Visual Analogue Scale (VAS) immediately after the surgery, 6 and 12 hours after the surgery
2. Analgesic use after surgery in the early postoperative period measured using data collected in patient medical records, defined as the mean and total number of morphine boluses needed, the number of doses of paracetamol, metamizole and ketoprofen needed per one-day
3. Scar quality assessment measured by the Patient and Observer Scar Assessment Scale

(POSAS) recorded on days 1, 8, 30 and 90 after surgery by both patient and clinician
4. Quality of life assessment after surgery measured using the 12-Item Short Form Survey (SF-12) on days 1, 8, 30 and 90 after surgery

Overall study start date
01/06/2016

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Diagnosis (or suspicion) of gynecological malignancy (ovarian, endometrial or cervical cancer) with the qualification for surgical treatment by laparotomy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
23 patients in the study group; 23 patients in the control group

Total final enrolment
46

Key exclusion criteria
1. Allergy for analgesics
2. Viral or bacterial local infections, coagulation disorders
3. Body mass index (BMI) > 40 kg/m2
4. Lack of consent for the study enrollment

Date of first enrolment
01/01/2018

Date of final enrolment
31/05/2019

Locations

Countries of recruitment

Poland

Study participating centre
Department of Obstetrics, Women's Diseases and Oncogynecology
National Medical Institute of the Ministry of the Interior and Administration in Warsaw
Wołoska 137
Warszawa
Poland
02-507

Study participating centre
Department of Obstetrics and Gynecology, Institute of Mother and Child
Kasprzaka 17a
Warszawa
Poland
01-211

Sponsor information

Organisation
National Medical Institute of the Ministry of the Interior and Administration

Sponsor details
Woloska 137
Warsaw
Poland
02-507
+48 47 722 15 52
ginekologia@cskmswia.gov.pl

Sponsor type
Hospital/treatment centre

Website
http://mib.gov.pl/

Organisation
Instytut Matki i Dziecka

Sponsor details
Kasprzaka 17a
Warszawa

Poland
01-211
+48223277044
klinika.poloznictwa@imid.med.pl

Sponsor type
Hospital/treatment centre

Website
https://icmh.org.bd/

ROR
https://ror.org/03v4km086

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Katarzyna Pankiewicz, e-mail: katarzyna.pankiewicz@imid.med.pl
Available for institutional review board-approved individual patient data meta-analysis 12 months after publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/10/2024	05/08/2025	Yes	No