

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

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<b>Registration date</b> 01/07/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/07/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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](mailto:tadeusz.issat@imid.med.pl)

## Contact information

### Type(s)

Public, Principal Investigator

### Contact name

Prof Tadeusz Issat

### ORCID ID

<http://orcid.org/0000-0002-3647-3550>

### Contact details

Kasprzaka 17a  
Warszawa  
Poland  
01-211  
+48223277044  
[tadeusz.issat@imid.med.pl](mailto:tadeusz.issat@imid.med.pl)

### Type(s)

Public, Scientific

### Contact name

Dr Katarzyna Pankiewicz

### ORCID ID

<http://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 salpingo-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/m<sup>2</sup>
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](mailto: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