

# A new method (nanosurgery and bioengineering treatment) of non-operative treatment of anterior cruciate ligament tears

**Submission date**  
21/03/2023

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
12/04/2023

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
07/05/2025

**Condition category**  
Injury, Occupational Diseases, Poisoning

☐ Individual participant data

## Plain English summary of protocol

### Background and study aims

Anterior cruciate ligament (ACL) tears account for 40%-50% of all ligamentous knee injuries. Most patients with ACL ruptures are treated with surgical procedures. In non-operative methods of ACL tears treatment, there is no objective, well-documented, repeatable, and standardized method. The current study aims to investigate ACL healing outcomes in patients who underwent non-operative, nanosurgery, and bioengineering treatment (NSBT).

### Who can participate?

Patients with a traumatic knee history and confirmed ACL tears

### What does the study involve?

Patients who meet all research criteria will be admitted to the trial and divided into 2 groups: the treatment group and the control group. Group I patients will be treated with a nanosurgery procedure with ultrasound-guided RP-hCM, RP-hCM is a modified platelet-rich plasma (PRP) injection. Group II patients will be treated with ultrasound-guided PRP injection into the joint capsule. The following variables in clinical assessment for all patients pre- and post-treatment were analyzed: WOMC scale, Lysholm knee scoring, VAS, and physical examination. All patients pre- and post-treatment were assessed by ultrasound and MRI examinations. Most of the patient groups were verified in the nano-scope procedure.

### What are the possible benefits and risks of participating?

A benefit of participating is a shorter recovery period taking only 12 weeks instead of 9 months. Possible risks include local pain after NSBT, failure of NSBT and conversion to an operative reconstruction of the ACL.

### Where is the study run from?

Wasilczyk Medical Clinic (Poland)

### When is the study starting and how long is it expected to run for?

June 2014 to July 2023

Who is funding the study?  
Wasilczyk Medical Clinic (Poland)

Who is the main contact?  
Mr Cezary Wasilczyk, wasilczyk.chirurg@gmail.com (Poland)

**Study website**  
<https://www.wasilczyk-usg.pl/>

## Contact information

**Type(s)**  
Principal Investigator

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
2015/NSBT/ACL

## Study information

**Scientific Title**  
Nano-surgical and bioengineering treatment of human anterior cruciate ligament tears with ultrasound-guided RP-hCM intake based on clinical, ultrasound, MRI, and nano-scope analyses

**Study objectives**

Nano-surgical and bioengineering treatment (NSBT) of human anterior cruciate ligament (ACL) tears with ultrasound-guided RP-hCM (rich plasma-human cell memory), a modified platelet-rich plasma that has potential cell memory, is a new way of non-operative ACL treatment

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 18/11/2021, the bioethics committee of the regional medical chamber in Warsaw (Komisja Bioetyczna Okręgowej Izby Lekarskiej W Warszawie; st. Pułowska, 18 02-512, Warsaw; +22 54 28 340, 42, 82; biuro@oilwaw.org.pl), ref: KB/1328/21

### **Study design**

Randomized double-blind 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

### **Health condition(s) or problem(s) studied**

Non-operative treatment of anterior cruciate ligament tears

### **Interventions**

Nanosurgery and bioengineering treatment (NSBT) under ultrasound guidance. Clinical exam-prospective, blind comparison to the gold standard.

The study uses a simple randomization model - sequentially numbered opaque, sealed envelopes to conceal the allocation. Patients will be consecutively enrolled and assigned to the study groups. The trial is double-blind, meaning that patients are blinded to which treatment group they are admitted to and are unblinded after the 6-week follow-up visit. The patients, the data collectors and the assessors are blinded. An independent examiner is blinded to the nano surgical and injection side and study group.

All nanosurgery procedures are standardized and are done in ambulatory conditions under local anaesthesia in a sterile way. The patients are arranged in the stomach position using posterior access. ACL fibres are defined in the ultrasound view. Using a needle (0.6-0.8 mm x 70-80 mm) under ultrasound guidance percutaneous Rp-hCM ACL intake is performed into the joint capsule

exactly to the ACL ruptured fibers. The method of Rp-hCM and PRP preparation was standardized. The NSBT procedure was performed by an experienced orthopedic surgeon in ambulatory conditions.

The modes of delivery of the intervention are face-to-face and individual.

The intervention occurs in ambulatory conditions in a treatment room in Wasilczyk Medica Clinic. The medical staff are trained nurses and doctors. Ultrasound Alpinion E-CUBE 15 Platinum is for all interventions.

### **Intervention Type**

Biological/Vaccine

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

RP-hCM

### **Primary outcome measure**

1. Pain measured using a visual analog scale (VAS) before treatment (1 day before NSBT) and after NSBT at baseline 24, 48 hours and next in 10 - 12 weeks
2. Patients' functional status in daily activities and pain assessed using the following measures before treatment (1 day before NSBT) and at the baseline 24, 48 hours and in 10 - 12 weeks:
  - 2.1. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)
  - 2.2. The Lysholm Knee scoring
3. Clinical knee instability measured using a physical examination and in Lachman test at baseline

### **Secondary outcome measures**

-

### **Overall study start date**

01/06/2014

### **Completion date**

01/07/2023

## **Eligibility**

### **Key inclusion criteria**

1. Positive Lachman and pivot shift test in physical examination
2. ACL tear confirmed in ultrasound and MRI examinations
3. No other coexisting injuries of the knee that would change treatment options to the operative procedure
4. Patient's signed informed consent to enrol in the trial

### **Participant type(s)**

Patient

### **Age group**

Mixed

**Sex**

Both

**Target number of participants**

30

**Total final enrolment**

25

**Key exclusion criteria**

1. Pregnancy
2. No patient signed informed consent to enrol in the trial

**Date of first enrolment**

01/01/2015

**Date of final enrolment**

30/07/2022

## **Locations**

**Countries of recruitment**

Poland

**Study participating centre**

**Wasilczyk Medical Clinic Warsaw**

02-953 Warsaw ul Kosiarzy 37/80

Warszawa

Poland

02-953

## **Sponsor information**

**Organisation**

Wasilczyk Medical Clinic

**Sponsor details**

Kosiarzy 37/80

Warsaw

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+48 502200590

wasilczyk.chirurg@gmail.com

**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.wasilczyk-usg.pl>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Wasilczyk Medical Clinic

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high impact peer reviewed journal

**Intention to publish date**

30/05/2023

**Individual participant data (IPD) sharing plan**

The datasets generated during the current study will be published as a supplement to the results publication

**IPD sharing plan summary**

Published as a supplement to the results publication

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		17/04/2025	07/05/2025	Yes	No
<a href="#">Results article</a>		24/04/2024	07/05/2025	Yes	No