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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

Registration date
12/04/2023

Overall study status
Completed

Last Edited
07/05/2025

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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)

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
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 Okregowej Izby Lekarskiej W Warszowie; st. Pulowska, 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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

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 Warsow
02-953 Warsaw ul Kosiarzy 37/80
Warszawa
Poland
02-953

Sponsor information

Organisation
Wasilczyk Medical Clinic

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Wasilczyk Medical Clinic

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be published as a suplement 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?
Results article		17/04/2025	07/05/2025	Yes	No
Results article		24/04/2024	07/05/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes