

# Autologous conditioned serum in the treatment of neck pain

<b>Submission date</b> 16/02/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/02/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/03/2025	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Neck pain is a very common health problem that has a negative impact on quality of life and significant burden on health systems. Autologous conditioned serum (ACS, Orthokine) injections are a safe and widespread form of treatment for musculoskeletal inflammatory and degenerative diseases. ACS is based on the competitive binding of proteins with the interleukin receptor (mainly IL-1) as well as anti-inflammatory and anti-oedematous effects. However, the optimal route of serum administration in the treatment of neck pain has not yet been proven. The aim of the study is to investigate whether infiltration of cervical fascia with ACS will have the same therapeutic efficacy as standard periarticular administration in the treatment of neck pain.

### Who can participate?

Patients aged 18 years and over with cervical (neck) pain

### What does the study involve?

Participants will be randomly assigned to one of two groups:

Group A: Autologous Conditioned Serum (ACS) injections into the fascial planes of the cervical section at palpation points under ultrasound guidance, four injections every 3 days.

Group B: Autologous Conditioned Serum (ACS) injections into the joint column of the cervical section under ultrasound guidance, four injections every 3 days.

The total duration of treatment is 10 days.

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

If the new technique proves equally effective compared to the standard technique of applying serum to the joint column, it will be an excellent treatment option for patients on chronic anticoagulant treatment where there is a significant risk of bleeding in perivertebral injections. Any intervention related to injection, even performed under ultrasound control, is associated with minimal risk of bleeding, nerve damage, infection, or temporary pain at the site of the drug administration. However, this risk is relatively low due to ultrasound control of needle guidance and extensive experience.

Where is the study run from?  
Sutherland Medical Center (Poland)

When is the study starting and how long is it expected to run for?  
December 2022 to December 2023

Who is funding the study?  
Sutherland Medical Center (Poland)

Who is the main contact?  
Dr Piotr Godek, piotrgodek.smc@gmail.com

## Contact information

**Type(s)**  
Principal Investigator

**Contact name**  
Dr Piotr Godek

**ORCID ID**  
<http://orcid.org/0000-0001-7809-1289>

**Contact details**  
Aleja Stanów Zjednoczonych 32/14  
Warszawa  
Poland  
04-036  
+48 (0)506 817 838  
piotrgodek.smc@gmail.com

## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
Nil known

## Study information

**Scientific Title**  
Comparison of the analgesic non-inferiority of ultrasound-guided injections of ACS (Orthokine) into the cervical fascial planes versus application along the cervical facet joints in patients with neck pain: A randomized, open-label, controlled clinical trial. (Protocol).

## **Acronym**

SPINE: Study on Pain In Neck Evaluation

## **Study objectives**

Current study hypothesis as of 29/03/2023:

Infiltration of cervical fascia with ACS will have the same therapeutic efficacy as standard periarticular administration in the treatment of neck pain

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Previous study hypothesis:

The application of autologous conditioned serum (ACS) to alleviate low-grade inflammation (LGI) in the fascial compartments reduces pain more than deep intra-articular injections, in the treatment of cervical spine pain.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 01/02/2023, Institutional Review Board at Wroclaw Medical University (50-367 Wroclaw, ul. J.Mikulicza-Radeckiego 4a, Poland; +48 (0)71 784 17 10; bioetyka@umed.wroc.pl), ref: KB-81/2022

## **Study design**

Prospective two-armed controlled randomized open-label interventional clinical trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

GP practice

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

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

Cervical pain of degenerative, overload, and post-traumatic origin

## **Interventions**

Randomization is carried out using computer-generated random numbers (simple randomization). The participants are randomly assigned to groups in a 1:1 ratio:

Group A: injections into the fascial planes of the cervical section at palpation points under ultrasound guidance, four Autologous Conditioned Serum (ACS) injections every 3 days

Group B: injections into the joint column of the cervical section under ultrasound guidance, four Autologous Conditioned Serum (ACS) injections every 3 days

The total duration of treatment is 10 days.

## **Intervention Type**

Other

## **Primary outcome measure**

Current primary outcome measure as of 29/03/2023:

1. Pain is assessed using the Numerical Rating Scale (NRS, 1-10) at baseline (T0) and 6 weeks (T1), and 12 weeks (T2) after the intervention
  2. Neck disability is assessed using the Neck Disability Index at baseline (T0) and 6 weeks (T1) and 12 weeks (T2) after the intervention
  3. Assessment of proprioception using the Dynamic Proprioception Test (DPT: shape outline error) at baseline (T0) and 6 weeks (T1) and 12 weeks (T2) after the intervention
- Three primary outcome criteria are defined and will be tested in hierarchical order: (1) Change in pain NRS from baseline to week 12 in the experimental group. (2) Change in pain NRS from baseline to week 12 in the control group. (3) Non-inferiority between groups in pain NRS from baseline to week 12.

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Previous primary outcome measure:

1. Pain is assessed using the Numerical Rating Scale (NRS, 1-10) at baseline and 1, 6, and 12 months after the intervention
2. Neck disability is assessed using the Neck Disability Index at baseline and 1, 6, and 12 months after the intervention

## **Secondary outcome measures**

Current secondary outcome measures as of 29/03/2023:

Safety will be assessed using the adverse event form.

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Previous secondary outcome measures:

Assessment of proprioception using the Dynamic Proprioception Test (shape tracing error). This test is used as a pre-treatment test and at the end of follow-up, i.e. 12 weeks after the end of therapy.

## **Overall study start date**

01/12/2022

## **Completion date**

31/12/2023

## **Eligibility**

**Key inclusion criteria**

1. Adults (aged 18 years and over)
2. Pain in the cervical section of degenerative, overload, post-traumatic origin
3. Consenting to the injection

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

100

**Key exclusion criteria**

1. Pregnant women
2. People with cancer
3. Presence of systemic inflammatory diseases
4. Injuries requiring surgical treatment
5. Anticoagulants that cannot be withdrawn
6. No consent to injection
7. No doctor approval

**Date of first enrolment**

01/04/2023

**Date of final enrolment**

31/12/2023

**Locations****Countries of recruitment**

Poland

**Study participating centre**

Sutherland Medical Center

Aleja Stanów Zjednoczonych 32/14

Warszawa

Poland

04-036

# Sponsor information

## Organisation

Sutherland Medical Center

## Sponsor details

Aleja Stanów Zjednoczonych 32/14

Warszawa

Poland

04-036

+48 (22) 673 60 43

klinika@smc.waw.pl

## Sponsor type

Hospital/treatment centre

## Website

<https://www.smc.waw.pl/>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

31/08/2024

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are available from the corresponding author Dr Piotr Godek (piotrgodek.smc@gmail.com) on reasonable request. Raw data (taking into account the anonymity of patients) will become available from the end of the study for 5 years. The research results will be passed on to other researchers in order to compare these results with the results of their own research.

## IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		26/02/2024	18/03/2025	Yes	No