

Autologous conditioned serum in the treatment of neck pain

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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

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 Wrocław Medical University (50-367 Wrocław, 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

Study type(s)

Treatment

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(s)

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.

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

Key secondary outcome(s)

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

Safety will be assessed using the adverse event form.

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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?
Protocol article		26/02/2024	18/03/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes