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Autologous conditioned serum in the treatment of neck pain

Submission date 16/02/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/02/2023	**Overall study status** Completed	
Last Edited 18/03/2025	**Condition category** Signs and Symptoms	

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

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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 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

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 deatails to request a participant informattion 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
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04-036

Sponsor information

Organisation
Sutherland Medical Center

Sponsor details
Aleja Stanów Zjednoczonych 32/14
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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?
Protocol article		26/02/2024	18/03/2025	Yes	No