Intra-articular injection of adipose-derived stromal vascular fraction in osteoarthritis of the temporomandibular joint

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The main objective of this study is to test the hypothesis that SVF alleviates pain and increases maximal interincisal mouth opening in patients with TMJ osteoarthritis.

Ethical review	Not approved
Status	Will not start
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON51137

Source
ToetsingOnline

Brief title
SVF injection in the TMJ

Condition

- Joint disorders

Synonym
Jaw complaints, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adipose tissue, Osteoarthritis, Stromal vascular fraction, Temporomandibular joint

Outcome measures

Primary outcome

The primary outcome of this study is the effect on pain and maximal

interincisal mouth opening.

Secondary outcome

The secondary objectives are the influences on oral health and mandibular

function.

Study description

Background summary

Stromal Vascular Fraction (SVF) from adipose tissue contains vascular cells, immune cells, adipose tissue-derived stromal cells, fibroblasts, and extracellular matrix with bound growth factors. Recent literature shows that SVF modulates inflammation. The hypothesis is that injection of SVF into the temporomandibular joint (TMJ) reduces inflammation in TMJ osteoarthritis.

Study objective

The main objective of this study is to test the hypothesis that SVF alleviates pain and increases maximal interincisal mouth opening in patients with TMJ osteoarthritis.

Study design

Double-blind sham surgery-controlled intervention study

Intervention

Both groups receive single-needle arthrocentesis of the joint. The intervention group receives abdominal liposuction and subsequent injection of the adipose-derived stromal vascular fraction in the upper TMJ space. Sham

liposuction will be performed in the control group by making a small abdominal incision to imitate the liposuction procedure.

Study burden and risks

Patients in the intervention group undergo both liposuction and intra-articular injection of SVF. SVF will be produced in a biological safety cabinet with laminary air flow provided by the UMCGC department of Clinical Pharmacy and Pharmacology at the treatment room to reduce risk of contamination. However, risks associated with intra-articular injection are infectious arthritis, worsening of the pain or the need for re-intervention. The management of infectious arthritis is antibiotics and flushing the joint through arthrocentesis. In the case that SVF seems to be the cause of worsening of the pain or limitation of the mouth opening, SVF can be removed by arthrocentesis and subsequent flushing with saline. Therefore, a risk for re-intervention is plausible. However, no serious adverse events or systemic complications can be expected of these locally administered injections. In addition to this, liposuction could possibly elicit some minor physical discomfort and an abdominal bruise. The benefits are hypothesized to be a long-term resolution of pain of the temporomandibular joint at rest or during movement and an improvement of maximal interincisal opening.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age between 18-70 years
* Chronic nociceptive pain in the TMJ region, aggravated by protrusion, maximal mouth opening, lateral excursions and/or chewing of at least 2 months
* Wilkes stages III or IV (internal derangement)
* Limited maximal interincisal opening (< 35 mm and > 15 mm)
* Pain still present after two weeks of a NSAID (i.e. ibuprofen 600 mg three times daily, or diclophenac 50 mg 3td, or napoxen 500 mg 2 td)
* Pain disappears after diagnostic intra-articular injection

Exclusion criteria

* Edentulous (no dentition)
* Previous treatments acting on cartilage or bone metabolism (eg, oral or intravenous bisphosphonates <1 year previously, strontium ranelate or teriparatide or raloxifene <7 days prior to selection, and oral glucosamine *1500 mg/day and chondroitin sulphate <3 months previously)
* Concurrent use of anti-inflammatory medication, steroids, muscle relaxants or antidepressants
* Previous TMJ traumas and fractures
* Previous TMJ surgeries, previous intra-articular injections < 1 year before
* Bilateral severe TMJ derangements
* Bony or fibrotic ankylosis of the TMJ
* Known history of diabetes mellitus type 1 or 2
* Known history of HIV
* Serious systemic diseases, rheumatic disease or infectious/inflammatory diseases affecting the skin of the area of the TMJ
* Pregnancy
* Coagulation disorders
* BMI <15

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cells autologous

Ethics review

Not approved

Date:	31-05-2021
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2021-000124-35-NL
CCMO	NL76480.000.21
Other	NL9181