Intra-articular injection of stromal vascular fraction from adipose tissue in osteoartritis of the temporomandibular joint

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The main objective is to objectify if the injection of SVF influences the pain of the TMJ during movement. Secondary objectives are pain during rest, maximum mouth opening, and function evaluation.

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

Summary

ID

NL-OMON44586

Source
ToetsingOnline

Brief title
SVF injection in TMJ

Condition

- Joint disorders

Synonym
jaw inflammation, Osteoartritis

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 endpoint is VAS pain scale (during movement and at rest) at

baseline, and at 3, 12 and 26 weeks.

Secondary outcome

Secondary outcome variables are maximal mouth opening at baseline, and at 3, 12

and 26 weeks. Other outcome variables are based on patient questionnaires MFIQ

and OHIP, at baseline, and after 3, 12, 26 weeks; complications during follow

up; analysis of synovial cytokines at baseline and at 26 weeks; analysis of

nucleated cells and characterization of the SVF in the intervention group.

Study description

Background summary

Stromal Vascular Fraction (SVF) from adipose tissue contains vascular cells, immune cells, adipose tissue- derived stromal/stem cells, fibroblasts, and extracellular matrix. Recent literature shows that SVF could modulate inflammation. The hypothesis is that the injection of SVF into the temporomandibular joint (TMJ) reduces inflammation in TMJ-disorders.

Study objective

The main objective is to objectify if the injection of SVF influences the pain of the TMJ during movement. Secondary objectives are pain during rest, maximum mouth opening, and function evaluation.

Study design

Pilot study with a single blind randomized controlled set up.

Intervention

Control intervention is single-needle arthrocentesis of the temporomandibular joint space. Study intervention is single-needle puncture arhtrocentesis of the upper TMJ space with the injection of SVF, obtained by abdominal liposuction.

Study burden and risks

It is likely that patients in the investigational group might have physical discomfort (bruise) of the abdominal liposuction. Liposuction is a low risk procedure in this study population and no other complications are expected other than abdominal discomfort. The risk of abdominal bruise is acceptable for the hypothesized therapeutic benefit caused by the immunomodulatory effect of the SVF in the TMJ. Because this procedures is never been used in the TMJ, an extra safety protocol is made to act directly (echography, other imaging) in case of complications, complains or concerns of the physician.

Contacts

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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 18-60 years;Pain in the TMJ region;Pain still present after two weeks of ibuprofen 600 mg three times daily (exclusion of acute inflammatory pain) ;Pain disappears after intra-articular injection (Ultracain forte, Aventis Pharma, Hoevelaken, The Netherlands) ;Pain still present (VAS during movement more than 20mm) after 3 weeks after an initial arthrocentesis.

Exclusion criteria

Systemic rheumatic disease ;Bony ankylosis of the TMJ ;Incompetence to speak the Dutch or English language ;Pregnancy ;Concurrent use of anti-inflammatory medication, steroids, muscle relaxants or antidepressants ;Unwillingness to receive one of the study treatments ;Prior open TMJ surgery ;Prior to liposuction;Coagulation disorders;BMI >18 ;BMI >25;Abnormalities in bloodanalysis

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20

Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cells autologous

Ethics review

Not approved

Date:	24-08-2017
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	EUCTR2017-002260-40-NL
CCMO	NL62517.000.17