

Swiss VISCOsupplementation Trial 1

Submission date 14/05/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/07/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/12/2007	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym
SVISCOT-1

Study objectives

To determine the comparative effectiveness, cost-utility and safety of preparations with different chemical structures and origins used for viscosupplementation in knee Osteoarthritis (OA).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Osteoarthritis (OA) of the knee

Interventions

Patients will be allocated to one of three different preparations, a cross-linked formulation (Synvisc®) and non-cross-linked preparations of different origin (Orthovisc® and Ostenil®). Patients will undergo up to three treatment cycles per knee (one cycle consisting of three injections), with not more than one treatment cycle per knee every 6 months and the last injection administered not later than 18 months post-randomisation.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Orthovisc®, Ostenil®, Synvisc®

Primary outcome(s)

Western Ontario and McMaster Universities osteoarthritis index (WOMAC) pain sub-scores.

Key secondary outcome(s)

Cost-utility based on health related quality of life measured by EuroQoL and self-reported healthcare utilisation for osteoarthritis

Completion date

31/12/2004

Eligibility

Key inclusion criteria

1. Men and non-pregnant women with radiologically confirmed symptomatic OA of the knee for at least 6 months
2. Pain on most days for the previous 3 months
3. Fulfil American College of Rheumatology (ACR) clinical criteria for OA of the knee:
 - 3.1. Have an ACR functional class rating of II to IV
 - 3.2. Failed to respond sufficiently
 - 3.3. Intolerant to conservative treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/05/2002

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

Switzerland

Study participating centre

Departments of Social and Preventive Medicine and Rheumatology

Berne

Switzerland

3012

Sponsor information

Organisation

Swiss Federal Office of Social Insurance (OFAS) (Switzerland)

ROR

<https://ror.org/03zv4m970>

Funder(s)

Funder type

Government

Funder Name

The Swiss Federal Office of Social Insurances (Switzerland) - funding protocol development and implementation

Funder Name

The manufacturers do not provide any funding for the trial.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/11/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes