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Swiss VISCOsupplementation Trial 1

Submission date	Recruitment status	[_] Prospectively registered
14/05/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/07/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/12/2007	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ispm.unibe.ch/research/ongprojects_epstat/sviscot-1.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/05/2002

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

Age group
Not Specified

Sex
Both

Target number of participants
600

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)

Sponsor details
Effingerstrasse 20
Berne
Switzerland
3003

Sponsor type
Government

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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