Intraarticular Application of Opioids versus Glucocorticoids versus Placebo in Gonarthritis

Recruitment status	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
• •	Record updated in last year
	No longer recruiting Overall study status

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

Assessment of efficacy and safety of intraarticular applicated Morphine versus Dexamethasone versus Placebo in gonarthritis in inflammatory rheumatic disease

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)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Gonarthritis in inflammatory rheumatic disease

Interventions

Single injection of Morphine 3 mg or Dexamethasone 4 mg or Placebo during needle arthroscopy. Rearthroscopy after 7 days.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Morphine, Dexamethasone

Primary outcome measure

Improvement of VAS pain of at least 20 mm on a 0-100 scale.

Secondary outcome measures

Impovement of a numeric pain scale, sleep quality, global daily activity, knee mobility with Lysholm and Gilquist Score, Western Ontario McMaster Universities Osteoarthritis (WOMAC) index, relief of pain on a numeric scale from 0-3.

Overall study start date

01/01/2004

Completion date

01/01/2006

Eligibility

Key inclusion criteria

- 1. Age 19-70
- 2. Gonarthritis with sonographically evident effusion in inflammatory rheumatic disease
- 3. Visual analogue score (VAS) pain >30 mm
- 4. Body weight 50-90 kg
- 5. Written informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Key exclusion criteria

- 1. Pregnancy, lactation
- 2. Severe or opportunistic infection, infection of the knee
- 3. Malignant diseases
- 4. Any other severe diseases
- 5. Platelets <100/nl, Quick <50
- 6. Significant findings during clinical examination
- 7. Participation in a clinical trial within 30 days before inclusion
- 8. Abuse of hard drugs, benzodiacepines, analgesics, alcohol
- 9. Therapy with anticoagulants

Date of first enrolment

01/01/2004

Date of final enrolment

01/01/2006

Locations

Countries of recruitment

Germany

Study participating centre Charité Campus Benjamin Franklin Berlin Germany 12200

Sponsor information

Organisation

Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

Sponsor details

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Sponsor type

University/education

Website

http://www.charite.de

ROR

https://ror.org/001w7jn25

Funder(s)

Funder type

Research organisation

Funder Name

German Research Foundation (Deutsche Forschungsgemeinschaft) KFO 100

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration