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Intraarticular Application of Opioids versus Glucocorticoids versus Placebo in Gonarthritis

Submission date	Recruitment status	[ ] Prospectively registered
24/08/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/10/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/02/2008	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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

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
Benjamin Franklin Campus
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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 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