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Intraarticular Application of Opioids versus Glucocorticoids versus Placebo in Gonarthritis

Submission date
24/08/2005

Recruitment status
No longer recruiting

Registration date
21/10/2005

Overall study status
Completed

Last Edited
06/02/2008

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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

Study type(s)
Treatment

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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Research organisation

Funder Name
German Research Foundation (Deutsche Forschungsgemeinschaft) KFO 100

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration