

Intraarticular Application of Opioids versus Glucocorticoids versus Placebo in Gonarthrosis

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Joachim Sieper

Contact details
Charité Campus Benjamin Franklin
Dept of Rheumatology
Hindenburgdamm 30
Berlin
Germany
12200
+49 (0)3084454414
joachim.sieper@charite.de

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives

Assessment of efficacy and safety of intraarticular applied Morphine versus Dexamethasone versus Placebo in gonarthrosis 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

Gonarthrosis in inflammatory rheumatic disease

Interventions

Single injection of Morphine 3 mg or Dexamethasone 4 mg or Placebo during needle arthroscopy. Re-arthroscopy 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)

Improvement 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. Gonarthrosis 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, benzodiazepines, 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