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Difference in indometacin and prednisolone in the treatment of gouty arthritis

Submission date	Recruitment status	[ ] Prospectively registered
15/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/02/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/02/2016	Musculoskeletal Diseases	

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
CRE-2008.466-T

Study information

Scientific Title
Comparison of oral prednisolone and oral indometacin in the treatment of acute gout-like arthritis: a multicentre double-blind randomised trial

Study objectives
Oral prednisolone is as effective as indometacin in treating gouty arthritis with less side effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee, 19/12/2008, ref: CRE-2008.466-T

Study design
Multicentre double-blind randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Gouty arthritis

Interventions
In Group 1 each patient will initially receive indometacin 50 mg orally, and six tablets of prednisolone-like placebo orally, and will then be observed for 120 minutes. Subsequently, the patient will be given a five day prescription of indometacin (50 mg orally eight hourly for two days follow by indometacin 25 mg eight hourly for another three days), and six tablets of prednisolone-like placebo once a day.

In Group 2 each patient will initially receive prednisolone 30 mg (six 5 mg tablets) orally, and indometacin-like placebo (two tablets) orally, and will then be observed for 120 minutes. After the initial treatment and observation, the patient will then be given a five day prescription of indometacin-like placebo (two tablets eight hourly for two days follow by one tablet eight hourly for a further three days) and prednisolone 30 mg orally once per day for five days.

All patients will be prescribed paracetamol 1 g six-hourly to be taken as required.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Prednisolone, indometacin

Primary outcome measure
Charted daily up to 14 days after the medication started:
1. Analgesic efficacy
2. Presence or absence of adverse effects

Secondary outcome measures
Charted daily up to 14 days after the medication started:
1. 36-item Short Form health survey (SF-36) score
2. Joint stiffness
3. Joint swelling
4. Joint tenderness
5. Length of hospital stay
6. Paracetamol use
7. Relapse rate within 14 days

Overall study start date
01/01/2010

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Aged greater than 18 years, either sex
2. Presenting to the Emergency Department between 9 am and 4 pm, Monday to Friday, from 1st January 2010 to 31st December 2011 with an acute arthritis suggestive of gout
3. Present within 3 days of symptom onset
4. Have a clinical diagnosis of an acute monoarthritis suggestive of gout
5. For the purpose of this study the diagnosis of acute gout is made if BOTH of the following TWO criteria are met:
5.1. Criteria 1: The presence of rapid onset of severe pain, swelling, tenderness and erythema of an affected joint, which is maximal by 6 to 12 hours
5.2. Criteria 2: The presence of one or more of the following:
5.2.1. Metatarsal-phalangeal (MTP) joint involvement (podagra); or
5.2.2. Knee or ankle joint involvement; or wrist or elbow joint involvement WITH either:
5.2.2.1. Gouty tophi present, or
5.2.2.2. Previous joint aspiration confirming the diagnosis of gout, or
5.2.2.3. The presence of hyperuricaemia, or

5.2.2.4. A clinical history of one or more clinical gouty arthritis attack
If none of B1 to B4 is present then we will seek to confirm the diagnosis by visual and microscopic examination of joint aspirate containing crystals.

Although joint aspiration and confirmation of the presence of uric acid crystals is not mandatory for inclusion in this study, nevertheless every patient will be asked whether they will consent to joint aspiration. Records will be kept of those that do and do not agree, and of those patients where aspiration is successful or unsuccessful.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100 per centre, total of 400

Key exclusion criteria
1. Suspicion of sepsis or other joint disease (e.g. rheumatoid arthritis)
2. Follow up is not possible because of lack of transport or lack of telephone contact
3. Any significant co-morbidity which would interfere with assessment
4. Dementia
5. Confusion
6. Active gastrointestinal symptoms
7. Renal insufficiency with serum creatinine greater than 200 umol/L
8. Bleeding disorder
9. Warfarin
10. Allergy to a study drug
11. Joint aspirate which excluded the diagnosis of gout

It is often not possible to definitively separate gout from septic arthritis on clinical grounds alone, but for this study, sepsis is likely if the patient has a temperature greater than 38°C, chills or rigors, a wound near to the affected joint, a history of immunosuppression, erythematous tracking along a lymphatic vessel or vein in the affected limb, lymphadenopathy, or a previous history of septic arthritis.

Date of first enrolment
01/01/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Hong Kong

Study participating centre
The Chinese University of Hong Kong
Shatin, NT
Hong Kong
852

Sponsor information

Organisation
Health, Welfare and Food Bureau (Hong Kong)

Sponsor details
Research Office
Government Secretariat
18/F, Murray Building
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Sponsor type
Government

Website
http://www.fhb.gov.hk/en/index.html

ROR
https://ror.org/03qh32912

Funder(s)

Funder type
Government

Funder Name
Health and Health Services Research Fund (HHSRF) (Hong Kong) - Special Administrative Region

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	05/04/2016		Yes	No