

Difference in indometacin and prednisolone in the treatment of gouty arthritis

Submission date 15/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/02/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 24/02/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

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 $\mu\text{mol/L}$
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

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Sponsor information

Organisation

Health, Welfare and Food Bureau (Hong Kong)

Sponsor details

Research Office

Government Secretariat

18/F, Murray Building

Garden Road

-

Hong Kong

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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