

Development of a complex intervention for the treatment of gout in primary care

Submission date 23/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 22/07/2013	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

Protocol serial number
7525

Study information

Scientific Title
Development of a complex intervention for the treatment of gout in primary care: a non-randomised observational treatment and qualitative study

Acronym

DCI-Gout

Study objectives

Phase 1 contains the development and feasibility work that is required prior to the community based RCT:

1. To develop a practical and acceptable nurse-led complex intervention for gout
2. To explore the potential barriers to such an intervention and adapt the intervention for optimal effectiveness
3. Address the following question: given optimal circumstances (i.e., a dedicated expert gout clinic), can application of the key component of the current management guidelines achieve the therapeutic target (serum uric acid [SUA] less than 360 $\mu\text{mol/L}$)?

To identify possible barriers to the delivery of, and adherence to the intervention, indepth interviews will be arranged with 12 participants with gout, GPs and practice nurses. In addition, 6 GPs and 6 practice nurses will also be invited to participate in a focus group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Nottingham Research Ethics Committee 2 approved on the 12th October 2009 (ref: 09/H0408/94)

Study design

Non-randomised observational treatment and qualitative study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Primary Care Research Network for England, Musculoskeletal; Subtopic: Not Assigned, Musculoskeletal (all Subtopics); Disease: Musculoskeletal, All Diseases

Interventions

Interventions will be based on the key elements of high quality gout management included in the EULAR and BSR guidelines. Following clinical assessment, study participants will be advised with respect to lifestyle modifications and, if relevant, will be prescribed licensed serum uric acid lowering medication (e.g., Allopurinol). The medication, dose and frequency will be dependent up on individual requirements. The number of attendances will also be based on the individual's clinical requirements.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Serum uric acid reduced to below 360 umol/L at 12 months

Key secondary outcome(s)

Clinical outcomes such as frequency of acute attacks and number and size of tophi will be recorded

Completion date

31/05/2010

Eligibility

Key inclusion criteria

1. Confirmed diagnosis of gout
2. SUA greater than 360 umol
3. Male and female, lower age limit of 30 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Gout cases with a SUA less than 360 umol/L (GPs asked not to contact patients with terminal illness or severe mental illness and those unable to give informed consent)

Date of first enrolment

01/02/2010

Date of final enrolment

31/05/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Nottingham City Hospital
Nottingham

United Kingdom
NG5 1PB

Sponsor information

Organisation

University of Nottingham (UK)

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

Charity

Funder Name

Arthritis Research Campaign (ARC) (UK) (ref: 18827)

Results and Publications

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	01/06/2013		Yes	No