ISRCTN44644781 https://doi.org/10.1186/ISRCTN44644781

Chondroitin sulphate for hand osteoarthritis: a randomised, placebo-controlled trial in primary care

Submission date
17/11/2016

Recruitment status
Stopped

Registration date
18/11/2016

Overall study status
Stopped

Last Edited
01/11/2017

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is a condition that causes joints to become painful and stiff. Painful hand OA affects 13-26% of adults aged 50 and over in the UK. The National Institute of Health and Care Excellence (NICE) has recently reviewed the costs and benefits of chondroitin sulphate in OA and decided against recommending it for use in the NHS on current evidence but highlighting the need for further research. One study found that chondroitin sulphate was better than a placebo (dummy drug) and had few side effects but the improvements in patients' pain and function after 6 months were generally small. However, this was a relatively small and short study, involving patients with more severe, advanced hand OA. Given the limited options for treatment of OA of the small joints of the hand, further research is now needed to determine whether chondroitin sulphate has long-term benefits on hand OA. To answer this question a longer term assessment of chondroitin sulphate is needed. The aim of this study is to find out whether chondroitin sulphate can improve hand pain and function over 12 months for people with hand OA.

Who can participate?
Patients aged 50 and over with hand OA

What does the study involve?
Participants are randomly allocated to one of two groups.
Participants in one group take chondroitin sulphate capsules daily for 2 years and also receive usual care. Participants in the other group take matching placebo (dummy) capsules daily for 2 years and also receive usual care. Any benefits of chondroitin sulphate may take weeks or months to emerge and so information is gathered from participants via postal questionnaires and telephone calls from a research nurse on seven occasions over a 2-year period. The calls are also an opportunity to check on how participants are getting on with their treatment and to support their involvement in the study. The focus is on the severity of hand pain over the first year, but changes in difficulties with daily activities due to the hand problem, possible side effects, other treatments, and general health are also assessed. Participants are invited to attend assessment clinics at the start of the study and at 1 and 2 years to test their hand

strength. Hand x-rays are taken at the start of the study and after two years to find out whether chondroitin sulphate slows down the disease process.

What are the possible benefits and risks of participating?
Although no direct benefit can be guaranteed, all participants will receive advice and information on better managing their hand problem. The results of this study will improve the treatment of hand OA in the future. All questions, examinations and x-rays in this study are already used to assess hand pain and hand problems, and any discomfort after a hand examination should be short-lasting. Radiation doses from x-ray examinations are extremely small in relation to those received from everyday living and therefore are not associated with any significant health risk. All medications can potentially cause side effects. Chondroitin sulphate has been used as a prescription medicine for the treatment of osteoarthritis symptoms for a number of years in several European countries but is not currently licensed in the UK. The most common side effects of chondroitin sulphate are gastrointestinal disorders (nausea, abdominal pain, bloating, diarrhoea or constipation), although these are rare (experienced by less than 1 in 1,000 people). Other possible side effects are oedema (water retention) or an allergic reaction, but these are extremely rare (experienced by less than 1 in 10,000 people).

Where is the study run from?
Keele Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
December 2015 to April 2020

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
Mrs Kendra Cooke

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2016-004670-18

Protocol serial number
RG-0004-16-IPCHS; HTA 14/45/04

Study information

Scientific Title
Finger osteoArthritis Chondroitin Treatment Used in addition to Advice and Leaflets

Acronym
FACTUAL

Study objectives
This trial is to find out whether 1200mg daily highly purified oral chondroitin sulphate, plus usual care, is effective, in terms of pain, function, structural disease progression, and cost-effective in patients with hand OA when compared to a placebo, plus usual care.

A 24-month Phase IV single-centre primary care, investigator-, practitioner- and participant-blinded, parallel-group, placebo-controlled, randomised, superiority trial of the effectiveness and cost-effectiveness of 1200mg daily highly purified oral chondroitin sulphate plus usual care for painful hand osteoarthritis in adults aged 50 years and over with a linked qualitative study

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/144504

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Single-centre, investigator-, practitioner- and participant-blinded, parallel-group, placebo-controlled, randomised superiority trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis of the hand

Interventions
Participants are randomised to one of two treatment groups via a web-based database:
1. Highly purified chondroitin sulphate 1200mg (3 x 400mg capsules) daily, oral, taken once per day for 2 years; plus usual care
2. Matching placebo 1200mg (3 x 400mg capsules) daily, oral, taken once per day for 2 years; plus usual care

Any benefits of chondroitin sulphate may take weeks or months to emerge and so information is gathered from participants via postal questionnaires and telephone calls from a research nurse on seven occasions over a 2-year period. The calls are also an opportunity to check on how participants are getting on with their treatment and to support their involvement in the study. The focus is on the severity of hand pain over the first year, but changes in difficulties with daily activities due to the hand problem, possible side effects, other treatments, and general health are also assessed. Participants are invited to attend assessment clinics at the start of the study and at 1 and 2 years to test their hand strength. Hand x-rays are taken at the start of the study and after two years to find out whether chondroitin sulphate slows down the disease process.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Highly purified chondroitin sulphate

Primary outcome(s)
Pain severity in the previous 2 weeks, measured using a 0-10 Numerical Rating Scale (NRS) at 0, 3, 6, 9 and 12 months

Key secondary outcome(s)
1. Secondary clinical effectiveness outcomes:
1.1. Severity and frequency of patient-reported hand pain and other hand symptoms, measured using AUSCAN, ACR criteria at 0, 3, 6, 9, 12 and 24 months
1.2. Patient-reported hand function, measured using FIHOA and AUSCAN at 0, 3, 6, 12 and 24 months
1.3. Patient global rating of change in hand problem and other composite outcomes, measured using global improvement measure, OMERACT-OARSI at 3, 6, 12 and 24 months
1.4. Performance-based measures of hand function, measured using GAT and grip/pinch strength measures at 0, 12 and 24 months
1.5. Pain at other joint sites, measured using 0-10 NRS at 0, 3, 6, 12 and 24 months
1.6. Patient-reported general health, measured using SF-12 v2 at 0, 12 and 24 months
1.7. Patient-reported mood, measured using HADS at 0, 12 and 24 months
1.8. (Serious) adverse events, measured at 1, 3, 6, 9, 12, 18 and 24 months
2. Cost-effectiveness, measured using EuroQoL 5D-5L, self-report cost data at 0, 3, 6, 12 and 24 months
3. Structural disease progression of hand OA, measured using summed score for finger joints (DIP, PIP, thumb IP) Kallman (0-180), summed score for finger and thumb joints (DIP, PIP, thumb IP, CMC, TS across both hands) (0-208), summed score for base of thumb joints (CMC, TS) (0-28), mean score per feature, mean score per joint group per feature, bilateral hand radiographs, at 0 and 24 months

Completion date
30/04/2020

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Aged 50 years and over
2. Fulfilling the American College of Rheumatology (ACR) definition of symptomatic hand OA
3. Hand pain ≥4/10 NRS in at least one hand
4. Hand pain is present on some, most or all days in the past month
5. Able to have bilateral hand radiographs
6. Stable medicines/treatment regime for pain
7. Ability to understand and capable of giving written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Red flags e.g. history of serious illness or disease (e.g. stroke), progressive neurological signs, acute swollen joint; fractures or significant injury or surgery to the wrist or hand in the last 3 months
2. Inflammatory arthritis (e.g. rheumatoid arthritis, psoriatic arthritis)
3. Previous use of chondroitin sulphate – ever*/within last 3 months (*subject to internal pilot)
4. Recent (past 3 months) use of steroids (oral, intra-muscular or intra-articular)
5. Recent (past 3 months) use of glucosamine sulphate/hydrochloride
6. Recent (past 3 months) plain x-rays of the hand(s)
7. Contra-indications to the trial medication (significant hypersensitivity to the active ingredient or to any of the excipients; pregnancy or breastfeeding)
8. Isolated thumb base (carpometacarpal joint) OA
9. Severe comorbidities (severe liver disease, uncontrolled asthma, severe renal disease, congestive cardiac failure, malignancy, known clotting disorders, anticoagulants)
10. Vulnerable individuals (e.g. psychiatric illness, learning difficulties, dementia, terminal illness and severe enduring mental ill health)
11. Known diagnosis of HIV or hepatitis

Date of first enrolment
01/07/2017

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Keele Clinical Trials Unit
Keele University
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Sponsor information

Organisation
Keele University

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Christian Mallen.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes