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Foot disease in Juvenile Idiopathic Arthritis: foot care trial

Submission date
05/06/2012

Recruitment status
No longer recruiting

Registration date
16/08/2012

Overall study status
Completed

Last Edited
14/11/2018

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Juvenile idiopathic arthritis (JIA) is the most common rheumatic (joint) disease in childhood. Active inflammation persists in adulthood for at least 30–50% of JIA patients and continuing active disease over long periods leads to significant levels of disability. Studies suggest that foot problems are common, occurring in over 90% of cases and characterised by joint pain, restricted joints and deformity. Further problems such as irregular, asymmetrical limb growth and altered walking patterns are also common.
Treatment for foot and ankle disease in JIA has focused on the use of corticosteroid joint injections, physiotherapy, insoles and orthoses, and orthopaedic surgery as an adjunct to medical care to both resolve joint inflammation and to correct or maintain foot form and function. The early use of steroid injections is thought to rapidly resolve joint inflammation, protect against deformity and alleviate pain. Two studies using magnetic resonance imaging (MRI) to guide steroid injections in the foot and ankle, suggest that approximately 6-month remission can be achieved in about two thirds of cases accompanied by reduced pain and improved joint function and walking patterns. Custom-made foot orthoses (shoe inserts) have been evaluated in one study indicating short-term (3-month) reduction in pain and improved function and quality of life when compared to prefabricated 'off the shelf' insoles or athletic shoes worn alone. There is no evidence of combined therapies or integrated care for the treatment of foot problems in JIA. The study should make a significant contribution to our knowledge and understanding of the manifestations and treatment of an important arthritis in childhood, potentially leading to significant health benefits and new clinical guidelines and policy. The aim of this study is to evaluate the clinical and cost effectiveness of a new foot care programme for patients with JIA who have foot problems.

Who can participate?
We aim to recruit 60 children or adolescents aged less than or equal to 16 years of age who have been diagnosed with JIA, from the Royal Hospital for Sick Children, Yorkhill, Glasgow, Scotland (UK).

What does the study involve?
Eligible participants will be invited to attend their first appointment where they will be randomly allocated to either the treatment group or the control group. Over a 1-year period eligible

participants in the treatment group will be invited to attend for five appointments separated by a period of 3 months. These appointments will include foot assessments by a podiatrist, physiotherapist, paediatric rheumatologist and an ultrasonographer. After these examinations the teams of examiners will decide on a treatment plan for any foot problems detected. Participants in the control group will have their feet examined at the beginning of the trial, then will receive normal standard care by their usual paediatric rheumatologist. They will return in 1 year for an appointment for repeated foot examinations to be conducted. This study will allow comparison between a team approach to the treatment of foot problems, compared to the 'standard' approach to foot problems normally delivered by the paediatric rheumatologist alone. No new or novel interventions (medications or devices) will be tested, and all treatments will be within the boundaries of normal clinical practice.

What are the possible benefits and risks of participating?
We would expect that the treatments offered in both groups will lead to an improvement in the care of arthritis-related foot problems. We will use the information we gain from both groups to improve foot care services for children, teenagers and adults with arthritis. The main disadvantage of taking part is that participants may be asked to give up some of their own time. We will try to make sure study visits coincide with participants' routine appointments. We are not testing any new treatments and all are used in routine clinical practice.

Where is the study run from?
The study was set up by Glasgow Caledonian University in collaboration with the University of Glasgow and the Paediatric Rheumatology Department at the Royal Hospital for Sick Children, Yorkhill, Glasgow. The trial will be conducted at the Outpatients Department at the Royal Hospital for Sick Children.

When is the study starting and how long is it expected to run for?
The study started in March 2009 and was completed in February 2011. Participants were enrolled for a period of 1 year. Recruitment was completed in February 2010.

Who is funding the study?
Arthritis Research UK.

Who is the main contact?
Dr Gordon J Hendry (Gordon.hendry@uws.edu.au)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
UKCRN5045

Study information

Scientific Title
Foot disease in Juvenile Idiopathic Arthritis (FiJIA): a randomised controlled trial of an intensive foot care programme

Acronym
FiJIA

Study objectives
It is hypothesised that there will be a significant difference between the usual care and the new foot care programme in terms of foot related impairment as measured by the primary outcome measure (The Juvenile Arthritis Foot Disability Index).

The null hypothesis is that there will be no difference between the usual care and the new foot care programme in terms of foot related impairment as measured by the primary outcome measure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Glasgow West Local Research Ethics Committee - Tennent Institute, Western Infirmary, Glasgow, reference: 06/S0703129

Study design
Phase II non-pharmacological exploratory 1 year two-arm randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Inflammatory foot disease in juvenile idiopathic arthritis

Interventions
Usual care
Participants randomised to usual care (standard podiatry) will receive normal outpatient medical care. Those in current receipt of foot care via (either adult or paediatric) podiatry services will

continue to receive care, while new referrals will also be permitted. Referrals will be monitored to ensure that medical staff referral patterns do not change once the study has started.

Intervention
Following ultrasound (US) identification of the anatomical structures involved by inflammatory lesions, and altered foot and lower limb function by instrumented gait analysis, a plan of appropriate clinical action will be taken by the (paediatric and adult) rheumatologists, the podiatrists and physiotherapist. If intra-articular joint injections are to be prescribed by the rheumatologists, then these will be conducted using ultrasound guidance within 1 month of initial consultation. The care plans will be agreed through discussion between the multi-disciplinary team based on their interpretation of the initial assessments. Participants will receive individualised care packages comprising combinations of foot orthoses and footwear treatments, physical therapies including stretching and muscle strengthening and standard podiatry care for problems such as skin callus and in- growing toenail; these will be delivered on the same day where possible. Customised orthoses will be manufactured via an external laboratory (Firefly Orthoses, Sligo, Ireland) according to the standardised order form, and will be ready for fitting within two weeks. As part of the new programme, rapid podiatry access will also be provided for unscheduled care episodes such as skin and softtissue foot infections, predominantly in-growing toenail, associated with disease modifying therapies. Finally, further multidisciplinary care will be used to include orthotists services when non-standard ankle/foot orthoses are indicated. Clinicians will use a core set of outcomes to chart progress and to modify individual treatment programmes during the trial period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Juvenile Arthritis Foot Disability Index (JAFI) (Andre et al, 2004). This questionnaire is organised by three dimensions related to impairment (9 items), activity limitation (14 items) and participation restriction (4 items) with a 5-point Likert scale for each item. Each point on the 5-point likert scale represents the frequency of the foot problem stated for that particular item during the past week (0 = Never, 1 = Occasionally/Less than once a week, 2 = Sometimes/Once a week, 3 = Frequently/Two to three times a week, and 4 = Always). Median scores are computed for each dimension. The JAFI is completed by parents of children <10 years and self-completed by adolescent children = 10 years of age. It has been shown to be to be valid and reliable for assessing foot-related impairment and disability among children/adolescents with JIA.

This questionnaire will be administered at baseline, then 6 (by post) and 12 months from baseline. The exploratory nature of the trial will permit in-depth examination of the suitability of the JAFI as a primary outcome measure for use in definitive multicentre trials.

Key secondary outcome(s))
1. Functional impairment using the childhood health assessment questionnaire (CHAQ), a valid and reliable instrument for measuring global functional status in children with JIA
2. Self- and proxy-reported health-related quality of life (HRQoL) using the EQ-5D-Y (patients) and EQ-5D-3L (parents/guardians) questionnaires, which are both comparable, valid and reliable generic measures of HRQoL in children/adolescents and adults
3. Disease activity using the American College of Rheumatology (ACR) core variables for JIA

(minus erythrocyte sedimentation rate)
4. Localised foot disease activity using summated clinical examination indices of tenderness and swelling
5. Foot deformity score using the structural index
6. Localised foot disease activity using summated musculoskeletal ultrasound examination indices of effusion, synovial hypertrophy, erosion, and power Doppler signal

Completion date
01/02/2011

Eligibility

Key inclusion criteria
1. All participants must have JIA diagnosed by their consultant rheumatologist, according to the International League of Associations for Rheumatology (ILAR) 2004 criteria. In addition, participants are to be included if they satisfy one of the following:
2. Lower limb arthritis of two or more large joints (hips, knees, ankles and subtalar joints).
3. Widespread polyarthritis involving large and small joints

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients with only upper limb, jaw, or neck involvement only will be excluded, along with those unable to cooperate with the study. Participants may also be excluded from the study (prior to randomisation) on the basis that: -
1. Any lesion detected during the ultrasound foot scan is not typical of synovitis (for example tumour, septic arthritis)
2. The lesion may require biopsy
3. The lesion requires referral for a second opinion

Date of first enrolment
01/03/2009

Date of final enrolment
01/02/2010

Locations

Countries of recruitment
United Kingdom

Australia

Study participating centre
University of Western Sydney
Penrith
Australia
2751

Sponsor information

Organisation
Glasgow Caledonian University (UK)

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK (UK) (ref:18076)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	01/05/2013		Yes	No
Protocol article	protocol	30/06/2009		Yes	No