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What is the clinical effectiveness of hydrotherapy in maintaining physical function in people with Duchenne muscular dystrophy?

Submission date 12/06/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/06/2014	**Overall study status** Completed	
Last Edited 31/03/2017	**Condition category** Nervous System 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
16831

Study information

Scientific Title
What is the clinical effectiveness of hydrotherapy in maintaining physical function in people with Duchenne muscular dystrophy?

Acronym
Hydrotherapy for Duchenne Muscular Dystrophy (DMD)

Study objectives
Duchenne muscular dystrophy (DMD) is a rare disease mainly affecting boys. DMD causes muscle cells to gradually break down so that with time, a patients muscles become weak to the point where they are unable to conduct many of the activities they used to. There is no cure for this disease, but doctors and physiotherapists try to slow down its progression and the development of complications by prescribing steroids and a physical management programme. Clinical experience shows that physical activity helps to maintain functional abilities. Mostly physical management programmes are done on dry land. However they can also be performed in warm water, under supervision by a physiotherapist; this is known as 'hydrotherapy' or 'aquatic therapy'. Hydrotherapy enables affected people to perform exercises which may not be possible on land due to the support provided by the water. Additionally the activity is seen as fun for them and their carers. Despite this, hydrotherapy is difficult to access in many places in the UK. Many NHS trusts do not fund it or have not got the facilities to offer it. While we know people with DMD value hydrotherapy, we are not sure whether it really adds anything to land-based exercises alone in terms of helping with walking and other daily activities. We are therefore undertaking a small scale pilot study to help decide if a larger scale trial would be feasible and if so, how we should best conduct it.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/EE/0204

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied
Topic: Children, Genetics; Subtopic: All Diagnoses, Genetics Research and Congenital Disorders (all subtopics); Disease: Genetics Research and Congenital Disorders, All Diseases

Interventions
Participants will be allocated on a ratio of 1:1 using simple randomisation with permuted blinded block size to:
1. Control group to receive optimised land-based exercises (as defined by local community physiotherapy services and recorded by trial team) (n=20)
2. The intervention group will receive the same plus hydrotherapy (30 min, twice weekly, for 6 months: active assisted and/or passive stretching regime; simulated or real functional activities; sub-maximal exercise) (n=20)

Study participants will be assessed for key outcome measures at 3 time points: consent and screen 1 visit; baseline visit; 26 week visit. We will collect information on a number of outcomes relating to the feasibility of conducting the trial which will include interviews with participants.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The feasibility of recruitment to the main trial

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2014

Completion date
30/05/2015

Eligibility

Key inclusion criteria
1. Genetically or biopsy confirmed DMD
2. Age 7-16 years
3. Established on glucocorticosteroids
4. North Star Ambulatory Assessment score 8-34 (stable over 4 weeks)
5. Able to complete 10 metre walk (6 minute walk test)

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1.More than a 20% variation between baseline North Star Ambulatory Assessment scores
2.Unable to commit to the programme of twice weekly hydrotherapy for 6 months
3.Any absolute contraindications or precautions to hydrotherapy

Date of first enrolment
01/12/2014

Date of final enrolment
30/05/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Health Services Research, School of Health & related Research (ScHARR) Regents Court
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
Sheffield Children's Hospital (UK)

Sponsor details

Western Bank
Sheffield
England
United Kingdom
S10 2TH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05mshxb09

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) (UK)

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	27/03/2017		Yes	No
HRA research summary			28/06/2023	No	No