

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	☒ Prospectively registered ☐ Protocol
Registration date 12/06/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 31/03/2017	Condition category Nervous System Diseases	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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 patient's 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

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Treatment

Study type(s)

Treatment

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(s)

The feasibility of recruitment to the main trial

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 Years

Upper age limit

16 Years

Sex

All

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

United Kingdom

England

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)

ROR

<https://ror.org/05mshxb09>

Funder(s)

Funder type

Government

Funder Name

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

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