D3 Creatine

Changes in muscle mass using the D3-creatine dilution method and function in DMD

Hub Summary

This study will use a new, non-invasive method of measuring muscle mass in patients with Duchenne muscular dystrophy. It is jointly funded by Duchenne UK, Muscular Dystrophy Association and Parent Project Muscular Dystrophy.

Participants will attend 3 6-monthly study visits over the course of the study in line with regular clinic visits. At the visit, participants will drink a small amount of D3-creatine, which can be used to measure changes in the muscle by testing urine samples. There are no risks involved with drinking the solution - it has been tested in children and adults of all ages, as well as boys with DMD, with no adverse events being recorded so far.

During the visit, the participant will also undergo functional tests, including the NSAA (North Star Ambulatory Assessment), upper limb assessment and timed tests. This will help to demonstrate whether changes in muscle mass will be reflected in changes in function.

Study Number: IRAS - 297878

Description by University of California, Berkeley

The D3Cr dilution method, along with a comprehensive evaluation of muscle function and strength, will be used to assess 1-year changes in functional capacity and muscle mass. In this way, variability in the rate of change will be assessed. The D3Cr dilution method is non-invasive and is well-suited for a multi-center trial.

They will be recruiting DMD participants between the ages of 5 – 25 years to represent a broad spectrum of disease state, and will recruit 150 patients across 3 sites: Duke University Medical Center, US, The University of Utah, US, Newcastle University, UK, and Newcastle upon Tyne NHS Foundation Trust, UK, in collaboration with the University of California, Berkeley, US.

Primary Outcome Measures

To measure longitudinal changes in functional capacity and functional skeletal muscle mass using the D3Cr dilution method in participants with DMD.

Can I take part?

Inclusion Criteria

- ✔ Confirmed diagnosis of DMD based on genetic testing and clinical history consistent with the diagnosis.
- ✔ Gender: Male
- ✔ For ambulatory patients: ability to walk 10 metres

Exclusion Criteria

- ✖ Phenotypic and/or genetic and/or histological evidence of dystrophinopathy compatible with Becker Muscular Dystrophy
- ✖ Continued use of creatine supplements (no use of creatine supplements for at least 2 months prior to enrolment).

For contact details and to find out more, please refer to dmdhub.org.

Trial Status
Fully recruited

UK Locations
Newcastle, Fully recruited

Trial Sponsor
University of California, Berkeley

Recruitment Target
150

Mutation Specific
Non-mutation specific therapies

Ambulatory
Ambulant and non-ambulant

Age
5-25

Therapeutic Category
Outcome Measures

Muscle Biopsy
No Muscle Biopsy Required

MRI
No

Phase
Observational

Length Of Participation
52 weeks

dmdhub.org

Duchenne UK

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