

# Hydrotherapy in mucopolysaccharidosis II

<b>Submission date</b> 23/10/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 25/10/2023	<b>Overall study status</b> Completed	
<b>Last Edited</b> 10/11/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## Plain English summary of protocol

### Background and study aims

Hydrotherapy (also known as aquatic therapy) is exercise therapy in warm water delivered by a physiotherapist. The unique properties of warm water can improve the movement of stiff or swollen joints, provide relaxation, strengthen weak muscles and alleviate aches and pains. Hydrotherapy has been shown to be particularly effective for pain in other conditions as aquatic buoyancy potentially reduces weight-bearing stresses on joints, bones and muscles. Hydrotherapy also allows the performance of closed-chain exercises, which are potentially painful with greater weight bearing when out of water. The pain syndromes seen in mucopolysaccharidosis type II (MPS) patients are complex and often multifactorial with elements of neuropathic pain, musculoskeletal pain and frequently a mixed picture with both. Patients with MPS present with joint, bone, and muscle pain. Non-surgical approaches such as physiotherapy have been advocated as benefitting patients with MPS II. Anecdotal evidence has supported the benefits of hydrotherapy delivered by a physiotherapist in the physiotherapy management of MPS disorders. It has been shown to decrease joint stiffness, reduce pain and improve strength. However, there is limited high-quality evidence currently to support its use as a routine part of care for this group of patients. The main aim of this study is to evaluate the effectiveness of hydrotherapy either positively or negatively on the quality of life of MPS II patients on long-term enzyme replacement therapy (ERT).

### Who can participate?

Male patients aged 18-58 years with mucopolysaccharidosis type II

### What does the study involve?

The hydrotherapy session will last 30 minutes in a heated pool and an experienced physiotherapist will deliver the programme and assessments. Patients will be asked to attend such sessions once a week for 12 weeks. Prior to the study, at 6 weeks into the study and at the end of 12 weeks patients will be asked to complete a patient satisfaction questionnaire. No blood samples will be collected apart from usual blood tests as part of the routine care in the metabolic clinic.

### What are the possible benefits and risks of participating?

The study may have a direct benefit to MPS II patients and will help our understanding of the effectiveness of hydrotherapy in the management of joint pain, improved mobility and quality of life in adult patients with MPS type II. No serious risks have been identified. The rare but

possible risks include fatigue, trip/slip on entering the pool, and skin irritation. Water inhalation or drowning are risks of hydrotherapy in general.

Where is the study run from?

Salford Royal Organisation, Northern Care Alliance (UK)

When is the study starting and how long is it expected to run for?

June 2023 to October 2024

Who is funding the study?

MPS Society UK

Who is the main contact?

1. Karolina M Stepien, CI
2. Marie Meehan, Study Coordinator

## Contact information

### Type(s)

Scientific, Principal investigator

### Contact name

Dr Karolina M Stepien

### Contact details

Adult Inherited Metabolic Diseases  
Salford Royal NHS Foundation Trust  
Salford  
United Kingdom  
M6 8HD  
+44 (0)1612064365  
karolina.stepien@nca.nhs.uk

### Type(s)

Public

### Contact name

Ms Marie Meehan

### Contact details

Stott Lane  
Salford  
United Kingdom  
M6 8HD  
+44 (0)1612064365  
marie.meehan@nca.nhs.uk

## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

**Integrated Research Application System (IRAS)**

317767

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

22MET03-S, IRAS 317767, CPMS 56760

## **Study information**

**Scientific Title**

Does hydrotherapy alleviate pain and improve functional mobility in patients with mucopolysaccharidosis type II (Hunter syndrome)?

**Study objectives**

Hydrotherapy is effective for pain as aquatic buoyancy potentially reduces weight-bearing stresses on joints, bones and muscles. It improves range of movement and reduces reliance on walking aids and the need for painkillers.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 15/06/2023, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8014; gmsouth.rec@hra.nhs.uk), ref: 23/NW/1069

**Study design**

Randomized cross over trial

**Primary study design**

Interventional

**Study type(s)**

Efficacy, Prevention, Quality of life

**Health condition(s) or problem(s) studied**

Mucopolysaccharidosis type II

**Interventions**

Participants are randomised into two groups A and B. While group A initially receives the hydrotherapy treatment, group B receives nothing and completes pain and quality of life questionnaires. Then there is a washout period. Then group B receives the treatment whilst group A receives no therapy but completes the questionnaires. The outcome is measured before each treatment and between the treatments. This study design will give 10 data points for analysis. The hydrotherapy lasts 12 weeks and the control arm will last 12 weeks. Overall each patient will participate in the study over 24 weeks.

## **Intervention Type**

Other

## **Primary outcome(s)**

Quality of life assessed using the Short Form Health Survey 36 scale (performed by nurse) at baseline, 6 weeks and 12 weeks while undergoing hydrotherapy and then separately while in the non-intervention arm

## **Key secondary outcome(s)**

Assessed at baseline, at a 6- and 12-week follow-up unless stated otherwise:

1. Risk assessment at baseline
2. Symptom severity assessed using the Brief Pain Inventory and pain-related questionnaires related to anxiety (GAD-7), quality of life (PHQ9) and kinesiophobia (TSK11) (performed by pain specialist/nurse)
3. The objective LANSS score will be used to identify and exclude patients who suffer from predominantly neuropathic pain (rather than musculoskeletal nociceptive-driven pain). This assessment will be performed by a pain specialist.
4. Global impression of change for patients with learning difficulties as assessed by the MDT team (consultant, physiotherapist & nurse)
5. Physiotherapy assessment including joint range of movement, muscle strength, functional mobility using 'Timed Up and Go' and either a 6-minute walk test or 10-m walk test as appropriate (performed by a specialist physiotherapist)
6. Medication utilization assessed using questionnaires before and after the intervention (performed by a nurse)
7. Adverse event log from starting hydrotherapy e.g. balance problems after each hydrotherapy session
8. Patient satisfaction assessed using a questionnaire at the end of the study

## **Completion date**

30/10/2024

# **Eligibility**

## **Key inclusion criteria**

1. Adult MPS II patients (Hunter syndrome; all males aged 18-58 years), who suffer from joint pain and stiffness and/or post-surgical musculoskeletal pain, not responding to analgesic agents
2. Patients with reduced mobility and wheelchair reliance
3. Patients are able to give consent and feedback. In patients with limited capacity, their carers /parents may be asked to help complete the questionnaires.
4. Participants who pass the Trust hydrotherapy risk assessment at baseline

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Adult

**Lower age limit**

16 years

**Upper age limit**

58 years

**Sex**

Male

**Key exclusion criteria**

1. Contraindications to standard hydrotherapy: acute diarrhoea or vomiting, recent acute cerebral vascular accident (CVA)/deep venous thrombosis (DVT)/pulmonary embolism (PE), resting angina, resting shortness of breath, uncontrolled cardiac failure, weight in excess of evacuation equipment, proven chlorine allergy.
2. More severely incapacitated (severe learning needs) and/or immobile patients.
3. The objective Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) score will be used to identify and exclude patients who suffer from predominantly neuropathic pain (rather than musculoskeletal nociceptive-driven pain). This assessment will be performed by a pain specialist.

**Date of first enrolment**

02/10/2023

**Date of final enrolment**

30/09/2024

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Salford Royal Organisation, Northern Care Alliance NHS Foundation Trust**

Stott Lane

Salford

United Kingdom

M6 8HD

**Sponsor information****Organisation**

Salford Royal Organisation, Northern Care Alliance NHS Foundation Trust

# Funder(s)

## Funder type

Charity

## Funder Name

MPS Society UK

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

## IPD sharing plan summary

Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Poster results</a>		01/02/2025	10/11/2025	No	No