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Children's acceptability of furosemide

Submission date 10/01/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 31/01/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/02/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to assess the acceptability of an orodispersible formulation of furosemide in children.

Who can participate?
Children from birth up to their 12th birthday can participate. They have to be taking a whole mg dose of furosemide e.g. 2mg, not 2.3mg to be able to participate. They also need to be able to take the medicine orally i.e. not down a feeding tube.

What does the study involve?
The study involves replacing the child's normal dose of furosemide (usually a liquid formulation) with the orodispersible formulation of furosemide. The dose will be the same. The only difference is the formulation of the medicine.

What are the possible benefits and risks of participating?
A single-dose direct switch in the formulation used is likely to have very little impact on participants as the same dose/frequency of treatment which is clinically indicated will be given for one dose only as part of this acceptability study. The new formulation has also been shown to be bioequivalent (meaning the same dose is absorbed) to an existing licensed furosemide tablet in adults.

Where is the study run from?
Alder Hey Children's NHS Foundation Trust, UK

When is the study starting and how long is it expected to run for?
October 2023 to January 2025. The first patient was recruited on 18th June 2024 and recruitment is expected to run until the end of December 2024.

Who is funding the study?
Proveca Ltd, UK

Who is the main contact?
The chief investigator for the study is Dr Daniel Hawcutt, d.hawcutt@liverpool.ac.uk

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
339343

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PRO/FUR/002, CPMS 60685

Study information

Scientific Title
Acceptability of age-appropriate furosemide orodispersible tablets (ODTs) in the paediatric population

Acronym
CHAFfinch

Study objectives
To assess the acceptability of a new formulation of furosemide for children.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/04/2024, West Midlands - South Birmingham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8019; southbirmingham.rec@hra.nhs.uk), ref: 24/WM/0055

Study design
Single-centre palatability and acceptability observational study

Primary study design
Observational

Secondary study design
Palatability and acceptability

Study setting(s)
Hospital, Medical and other records

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
All patients taking oral furosemide and meeting the inclusion and exclusion criteria will be considered.

Interventions
This study investigates a single replacement dose exposure of an orodispersible tablet formulation of furosemide (dose given as per current prescription).

The clinical team will identify participants taking oral furosemide. The research staff are informed of potential participants and discuss the study with them and/or their parents. Assent /consent is taken. The participant is then given the orodispersible furosemide product (same dose) and is filmed taking this so that researchers can review the video afterwards to score the palatability of the medicine. The participant and/or parents/carer are also asked to complete a questionnaire on the acceptability of the medicine. The total study duration is expected to be less than 30 minutes. There is no follow-up for this study.

Intervention Type

Drug

Pharmaceutical study type(s)
Palatability and acceptability

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Furosemide

Primary outcome measure
Acceptability is measured with an adapted version of the composite endpoint using a score for swallowability at the time the participant takes the furosemide and a score for palatability performed by two researchers reviewing the videos that were taken of the participant taking the replacement dose

Secondary outcome measures
The number of participants willing to take the orodispersible tablet formulation of furosemide in the future was measured using the following questions in participant or parent/carer questionnaires after the dose is given:
Overall, how happy would you be to take this new medicine in the future?
Would you be happy to give your child this new medicine in the future?

Overall study start date
05/10/2023

Completion date
15/01/2025

Eligibility

Key inclusion criteria
1. Participants aged from birth (including pre-term neonates) to less than 12 years old (i.e up to their 12th birthday).
2. No limitation of nationalities, demographics, socio-economic or ethnic groups.
3. Written informed consent must be obtained from the child’s parent / carer with parental responsibility.
4. Consent needs to be sought from a legal guardian who has an appropriate understanding of written English. If this is not possible, an interpreter will be sought. Parents/carers must however have the capacity to be able to understand the study information.
5. Written assent will be sought for all study participants aged 6 years and over, where appropriate. Ability to assent will be judged on a case-by-case basis by the research team.
6. The participant (inpatient or outpatient) is currently taking an oral formulation of furosemide and has completed at least 48 hours of oral treatment, with no dose alterations planned.
7. The participant (in agreement with their legal guardian) is willing to be video recorded while the study medication is administered.
8. The clinical team and/or the participant’s parent / carer raise no concerns about the child’s involvement in this study.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
0 Days

Upper age limit
11 Years

Sex
Both

Target number of participants
10

Total final enrolment
10

Key exclusion criteria
1. Participants aged 12 years and older.
2. Participant(s) whose parent/guardian is unable to read and/or understand the study information sheet provided.
3. Child participant refuses to provide verbal assent to take part in the study, where appropriate.
4. Parent/carer unable or unwilling to give informed consent.
5. The participant has a known swallowing difficulty (with either solid or liquids).
6. The treating clinical team feel the participants' current prescribed dose of furosemide may need to change imminently i.e. their furosemide dose is too unstable/variable at present.
7. Participant is receiving their dose of oral furosemide via any type of enteral feeding tube such as nasogastric (NG) tube or percutaneous endoscopic gastrostomy (PEG).
8. The child has a known allergy (or intolerance) to furosemide or any of the excipients included within the new ODT furosemide formulation.
9. The treating clinical team feel there are family or social issues (e.g. pronounced family distress or child protection intervention) that would make it inappropriate to approach the family to take part in the study.

Date of first enrolment
18/06/2024

Date of final enrolment
10/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Alder Hey Children's NHS Foundation Trust
Eaton Road
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Sponsor information

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Proveca (United Kingdom)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Proveca Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the full datasets being commercially sensitive and potentially used to support marketing authorisation applications.

IPD sharing plan summary
Not expected to be made available