Gravity of Flow - The Flowsure clinical validation study protocol

Published: 11-12-2023
Last updated: 02-12-2024

The primary endpoint is the accuracy of urine production monitoring using the automated Flowsure monitor compared to the standard manual method of monitoring.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56545

Source
ToetsingOnline

Brief title
Gravity of Flow

Condition

- Other condition

Synonym
diuresis, urination

Health condition

de criculatie en de daarmee samenhangende urineproductie door de nieren

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W,NWO

Intervention

Keyword: Flow, Urine

Outcome measures

Primary outcome

The primary outcome event in Part A will be the accuracy of urine measurement over two set time interval (a nursing shift of 8 hours and a full 24 hours period) using manual monitoring and automated monitoring. The gold standard will be the total urine production measured in a measuring cup by draining the collection bag.

The primary outcome in part B of the study will accuracy of measurement over a set time interval (a nursing shift of 8 hours and a full 24 hours period) using manual monitoring and automated monitoring. Additional the completeness of the hourly diuresis registration will be compared between the manual and automated measurement groups.

Secondary outcome

Not applicable

Study description

Background summary

Current manual diuresis monitoring is too labor intensive to optimally monitor hospitalised patients with a urine catheter. The automated Flowsure monitor aims to automate diuresis monitoring.

Study objective

The primary endpoint is the accuracy of urine production monitoring using the automated Flowsure monitor compared to the standard manual method of

monitoring.

Study design

Part A is single arm intervention study in which patients will receive both the manual monitors and automated Flowsure monitor (both devices will be used in conjunction). Part B is a two-arm non-randomized non-blinded intervention study in which patients will be monitored with either the manual monitoring or automated Flowsure monitor (non-randomized and based on availability of the automated monitor).

Intervention

In part A patient will undergo double urine monitoring as they receive both the manual urine monitor and automated Flowsure monitor. In part B patients will be randomized to monitoring with the manual monitor or to automated monitoring with the automated Flowsure monitor.

Study burden and risks

There will likely be no direct benefit for patients participating in the study.
The societal/research benefit of the study lies in the potentially improved diuresis monitoring and registration in the medical record of the patient which will improve the quality of patient monitoring and therefore patient safety.
Risks: The foreseeable added risks associated with the use of Flowsure in Part A are negligible as using the automated monitor will be additive to the manual measurements. In part B patient will be monitored with either a manual monitor or the automated flowsure monitor. The foreseeable added risks associated with the use of Flowsure in part B is negligible because if Flowsure fails the hourly urine production can be estimated by dividing the total urine collection since monitoring started by the hours that have passed since insertion of the urine catheter.
Risk-benefit analysis: Since the expected clinical-scientific benefit of this study is estimated as large and the clinical investigation is, in the opinion of the investigators, proportional to the added risk associated with the use of the medical device which is estimated as low, the overall risk-benefit profile of the study is favorable.

Contacts

Public
Amsterdam UMC

Meibergdreef 9

Amsterdam 1105AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 18 years and older
- Currently hospitalized
- Currently for medical treatment (unrelated to the study have an urine catheter inserted
- Willing and able to provide informed consent

Exclusion criteria

Patients who:
- Do not have a urine catheter inserted
- Are known to have chronically no diuresis (e.g. patients on dialysis).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-04-2024
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name:	Flowsure
Registration:	No

Ethics review

Approved WMO

Date:	11-12-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84838.018.23