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Intrathecal pump refills at home or at the hospital

Submission date 18/11/2025	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 18/11/2025	**Overall study status** Ongoing	
Last Edited 19/11/2025	**Condition category** Other	

Plain English summary of protocol

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Additional identifiers

Study information

Scientific Title
Intrathecal pump refills at home or at the hospital: a randomized controlled crossover trial

Acronym
IMPROVE

Study objectives
The IMPROVE study is a randomized, controlled, cross-over trial designed to compare intrathecal pump refills performed at home with those carried out in the hospital. Intrathecal drug delivery (IDD) is used in patients with chronic pain or severe spasticity. Use of IDD requires the performance of pump refills about 4-6 times a year which may be a burdensome and stressful experience for patients and their caregivers. Hospital visits can increase stress, pain, and caregiver strain, while early pilot studies suggest home-based refills may be both safe and more comfortable.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/09/2025, UZ Brussel/VUB (Laarbeeklaan 101, Jette, 1090, Belgium; +32 24774111; ethiek@uzbrussel.be), ref: 1432025000188

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Intrathecal pump refill procedures

Interventions
Eighty-two adult patients in Belgium with an implanted intrathecal pump will be enrolled in the IMPROVE study. Each participant will undergo four refill procedures: two at home and two at the hospital, in randomized order.

To ensure allocation concealment, the randomization sequence was generated in advance and stored in a secure, access-restricted Excel log. Study duration contains 4 refill procedures for every patient, which entails max. 12 months.

Intervention Type
Other

Primary outcome(s)
1. Patient Comfort measured using General Comfort Questionnaire (GCQ) at at baseline and after each of the four refill procedures (postprocedural) through study completion

Key secondary outcome(s))
1. Quality of life measured using the McGill Quality of Life Questionnaire (MQOL) at at baseline and after each of the four refill procedures (postprocedural) through study completion

2. Health-related quality of life measured using the EuroQol with five dimensions and five levels (EQ-5D-5L) at at baseline and after each of the four refill procedures (postprocedural) through study completion

3. Pain intensity measured using the Visual Analogue Scale (VAS - 100 mm) in electronic format at at baseline and after each of the four refill procedures (postprocedural) through study completion

4. Pain interference in social, cognitive, emotional, physical, and recreational activities measured using the NIH-funded Patient-Reported Outcomes Measurement Information System Pain Interference measure at at baseline and after each of the four refill procedures (postprocedural) through study completion

5. Stress measured using Saliva samples will be collected to measure cortisol levels with synthetic salivettes at 5 minutes before the refill, immediately after the refill and 10 minutes after the refill procedure.

6. Anxiety measured using the State Trait Anxiety Inventory (STAI). at at baseline and after each of the four refill procedures (postprocedural) through study completion

7. Self-efficacy measured using the General Self-Efficacy (GSE) Scale at at baseline and after each of the four refill procedures (postprocedural) through study completion

8. Caregiver burden measured using the Zarit Burden Interview (ZBI) questionnaire at at baseline and after each of the four refill procedures (postprocedural) through study completion

9. Patient satisfaction measured using seven-point Likert scale at after each of the four refill procedures (postprocedural) through study completion

10. Tele-monitoring quality measured using using three different Likert scales to score 1) quality of audio, 2) quality of video, and 3) overall quality of the teleconsultation at after each refill procedure at home (2 times)

11. Duration of refill measured using stopwatch at during each refill procedure (4 times)

12. Patients will evaluate the overall safety of the procedure measured using a seven-point Likert scale. In addition, the researcher will assess safety on three levels: (1) overall perceived safety of the procedure using a seven-point Likert scale; (2) environmental safety, assessed through an open-ended question addressing any situations perceived as unsafe; and (3) the ability to perform the procedure in a clean and sterile manner, also evaluated via an open-ended question. at during and after each refill procedure (4 times)

13. Health expenditure measured using hospital claims data. All other healthcare-related costs will be gathered through telephone interviews with patients at four weeks after first refill and four weeks after second refill procedure.

14. Patient preference measured using by asking patients to indicate their preference (refill at home, refill in the hospital, no preference or other) for the location of their refills in the future at after the fourth refill procedure at study completion

15. Preferences across several scenarios measured using a discrete choice experiment at after the fourth refill procedure at study completion

Completion date
01/10/2028

Eligibility

Key inclusion criteria
1. Actively receiving Intrathecal drug delivery
2. Stable medication dosage for at least 3 months
3. Dutch, French or English speaking adults

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment

0

Key exclusion criteria
1. Life expectancy < 6 months
2. Patients planned for but not yet received Intrathecal drug delivery implant
3. No residence in Belgium

Date of first enrolment
15/10/2025

Date of final enrolment
01/10/2027

Locations

Countries of recruitment
Belgium

Sponsor information

Organisation
Vrije Universiteit Brussel

ROR
https://ror.org/006e5kg04

Funder(s)

Funder type

Funder Name
Fonds Wetenschappelijk Onderzoek

Alternative Name(s)
Research Foundation Flanders, Flemish Research Foundation, The FWO, Het FWO, FWO

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available