Smart blisters to monitor and support medication adherence: a usability study (SMART BLISTER)

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28033

Source
NTR

Brief title
SMART BLISTER

Health condition

None

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Aardex Group

Intervention

Outcome measures

Primary outcome

Usability of the MEMS EDP, measured by the System Usability Scale (SUS)

Secondary outcome

• Comparison of the MEMS EDP data with manual pill count
• Comparison of the MEMS EDP data with self-reported adherence,
• Technical assessment
• Qualitative evaluation

Study description

Background summary

A novel medication event monitoring system (MEMS®) has been developed in the form of a smart blister package (Electronic DosePak, EPD®). This study will aims to investigate usability of the MEMS EDP® smart blister system for use in trials at the University Medical Center Groningen and beyond.
We propose a pragmatic trial examining the acceptance and technical robustness of the MEMS EDP system. We will include 20 healthy volunteers (English speaking) with diverse age/sex/education.

The key objectives of this study:

• Perform analysis and validation of the MEMS EDP's robustness, accuracy and patient acceptance within a clinical study
• Initial investigation of benefits to health professionals and subjects when the MEMS EDP is used to support, measure, and monitor dispensing of medicines

Study objective

In order for the MEMS EPD to be used with patients taking medicines, we intend to show that the system is simple for patients to use, collects accurate data, performs as intended for the life of a trial and supports patients to better manage their medicines.

Study design

Subjects will have one digital meeting and two site visits:
• Prior to visit 1, all subjects will attend a (digital) general kick-off meeting with information on the study and have training on how to use the EDP.
• At Visit 1, they will receive the EPD in person (or by mail post if applicable).
• At Visit 2, they will return the blisters with a short one to one interview and are reminded to complete the online questionnaires (in English).

Intervention

All participants receive four MEMS EDP's containing 14 placebo tablets per blister. The placebo tablets are taken out twice daily (not intended to be ingested). The follow-up period is four weeks.

Contacts

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Eligibility criteria

Inclusion criteria

Subjects will be eligible for the trial if all the following criteria are met:
• age >18 years
• provide informed consent

Exclusion criteria

• Subject informs he/she will not be able to participate in the trial
• Withdrawal of informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9535
Other	METc UMCG : 2021/363

Study results