Patient acceptability and technical robustness of the Elucid Pill Connect system for use in clinical trials

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON19951

Source
NTR

Brief title
ELUCID

Health condition

Not applicable

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Percentage of pills dispensed according to intended dosing schedule

Secondary outcome

User acceptance (measured with the System Usability Scale and a self-designed questionnaire), investigator acceptance, technical validation (correct logging of dispense data, timing, battery life, sending of reminders, locking and temperature) and comparison with self-reported adherence according to the MARS questionnaire

Study description

Background summary

The Elucid Pill Connect system has been developed with the aim of providing novel insights into non-adherence and supporting patients to better manage their medicines. Improving adherence and increasing the accuracy of adherence data may also affect health outcomes and decrease health care utilisation and costs. We propose a pragmatic trial examining the patient acceptance and technical robustness of the ELucid Pill Connect system. In order for it 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 and supports medication adherence.

Study objective

The Elucid Pill Connect system dispenses all doses correctly and sends accurate data to the monitoring server that represents the subject’s non-adherence whilst enforcing the dose schedule.

Study design

T=0 and T= 2 weeks

Intervention

Provision of the Elucid Pill Connect System

Contacts

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Eligibility criteria

Inclusion criteria

(1) age >18 years, (2) own an Android or Iphone phone with the required OS versions, (3) are able to operate the mobile phone themselves and (4) provide informed consent.

Exclusion criteria

None

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:	Recruitment stopped
Start date (anticipated):	28-06-2019
Enrollment:	10
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-06-2019
Application type:	First submission

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	NL7835
Other	METC UMCG : METc 2019/332

Study results

Summary results

https://www.dovepress.com/user-acceptability-and-technical-robustness-evaluation-of-a-novel-smar-peer-reviewed-article-PPA