Postbariatric EArly discharge Controlled by Healthdot

Published: 16-12-2020
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To evaluate whether performing bariatric surgery as outpatient surgery is not inferior to the current treatment based on a combined outcome measure.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49644

Source
ToetsingOnline

Brief title
PEACH

Condition

- Other condition

Synonym
Outpatient surgery, vital sign measurement

Health condition

Monitoring vital signs of patients after standard bariatric surgery

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: No funding is provided by the sponsor of

this study to the hospital. This study is part of a umbrella agreement between Philips and Catharina Hospital.

Intervention

Keyword: bariatric surgery, outpatients, telemedicine

Outcome measures

Primary outcome

Primary objective:

To evaluate whether performing bariatric surgery as outpatient surgery is not

inferior to the current treatment based on a combined outcome measure.

Secondary outcome

Secondary objectives:

* To assess Patient satisfaction (on a scale of 1-10) in both groups

* To assess feasibility of outpatient recovery after standard bariatric surgery

by evaluating recruitment rate, adherence to protocol and randomization, and

the amount of missing data.

* To evaluate the percentage and total number of false-positive notifications

from the Healthdot system.

* To evaluate the percentage of missed events (i.e. false negatives) from the

Healthdot system.

* To evaluate the total number of missed minor events from the Healthdot system.

* To evaluate the outcome of patients who choose HD versus patients who were

randomized to HD on a combined outcome measure as defined for the primary

endpoint.

* To compare the number of adverse events in both groups

* To compare the use of pain medication during day of surgery until evening in both groups.

* To compare the clinical decisions made on basis of remote monitoring with the Healthdot system, to decisions which also include information from a telephone consultation

* To evaluate the impact of outpatient recovery after standard bariatric surgery and the Healthdot on patient and health professional satisfaction

* To evaluate the costs involved with outpatient recovery after standard bariatric surgery supported by Healthdot.

* To evaluate usability of the visualization of Healthdot data on the Guardian dashboard.

Study description

Background summary

This clinical investigation is a single center patient preference trial in a tertiary hospital in the Netherlands, designed to compare outcome of outpatient bariatric surgery enabled by measuring the vital signs heart rate and respiratory rate by the Healthdot at home to the current treatment. 200 patients will be recruited and can choose whether they receive outpatient surgery or the regular treatment. Patients in the outpatient group will leave hospital on the day of surgery. They will wear the Healthdot for 7 days at home and vital signs will be transmitted to the hospital to monitor recovery.

Study objective

To evaluate whether performing bariatric surgery as outpatient surgery is not inferior to the current treatment based on a combined outcome measure.

Study design

This is a single center clinical investigation

Intervention

Patients in the active group will receive a Healthdot after surgery and will leave the Hospital on the same day as surgery took place.

Study burden and risks

For the patients participating in this investigation no direct benefits have been identified. A potential benefit is that patients who are in the active group wearing the Healthdot are able to leave hospital one day early which could potentially lead to a higher patient satisfaction. Assessing patient satisfaction is one of the endpoints in this study. The only anticipated adverse device effect is an allergic reaction to the plaster used to locate the device on the skin of the patient. This is mitigated by excluding patients with known allergies to these kind of medical adhesives. Sending the patient home on the same day has been assessed in bariatric surgery in several studies and risks associated with this are considered low. Though the patients undergo surgery with the associated risks of this procedure this is not part of the study and the study does not influence the surgery risks. The placement of the devices will add some additional burden to the patient not related to her/his stay in hospital, however this additional burden is low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Adult (equal or greater than 18)
- Approval for primary bariatric surgery (gastric sleeve or bypass) by a multidisciplinary bariatric team
- Willing and able to sign informed consent form
- Able to understand instructions
- In possession of a telephone on which patient can be reached for the duration of participation (day 1-8)
- An adult person must be present at the same location as the patient during the first night following surgery who is able to mobilize help or seek medical care if necessary.

Exclusion criteria

- Patients of psychiatric wards, inmates of prisons, or other state institutions
- Investigator or any other team member involved directly or indirectly in the conduct of the clinical study
- Any skin condition, for example prior rash, discoloration, scars or open wounds at the area (lower left rib) where the HealthDot needs to be placed
- Known allergy for the tissue adhesive used in the Healthdot (white band-aid)
- Use of topical that is known to influence the skin at the test area (such as medical and non-medical creams or lotions)
- Patient with active implantable such as Implantable Cardioverter Defibrillator (ICD) and pacemaker
- Expected participation less than 8 days
- Left lower rib (place where Healthdot will be applied) is involved in the area of surgery, area of disinfection or area where bandages are needed.
- Patients with antibiotic resitant infections (e.g. MRSA)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2021
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Healthdot
Registration:	No

Ethics review

Approved WMO

Date:	16-12-2020
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL74503.015.20
Other	Registration will be done before first patient is included in clinical trials.gov.