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Promotion of dietetic treatment with enhanced salt taste using Salt Chip

Submission date	Recruitment status	[ ] Prospectively registered
10/07/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/07/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/07/2019	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Adequate dietary intake to satisfy the nutrition requirement is particularly crucial for the patients who undergo invasive surgery, such as open heart surgery and large vessel surgery, to maintain the nutritional status, reduce edema, and start cardiac rehabilitation as early as possible during the perioperative period. However, this is often hindered by the physical damages in the mouth, reduction of the pylorus movement, and the lowered motivation by the surgery. In addition, dietary restriction of salt with the intake less than 6.0 g/day, which is reported to be effective as a nutrition therapy for cardiovascular diseases, often leads to further reduction of dietary intake due to the low-salt taste.

We consider that dietetic treatment to increase the food intake and thus improve the nutrition status during the perioperative period is of importance for good recovery of the patients. In this clinical trial, we focus on salt since salt is one of the major contributors to good taste while the intake is strictly restricted for the cardiovascular patients. We used Salt Chip to enhance the salt taste without increasing the salt intake. Salt Chip is attached onto the back of the lower front tooth and deliver salt directly to the tongue, which enables the patients to perceive strong salt taste even with as low as 0.05 g of salt. Dietetic treatment with Salt Chip should increase the eating amount of patients who underwent open heart surgery, which will promote recovery of the activities of daily life.

Who can participate?
Patients who undergo open heart surgery without severe frailty.

What does the study involve?
Participants of Group S are asked to use Salt Chip at every meal during their stay at the hospital except the first meal after the surgery. The participants of control group C do not use Salt Chip. The eating rate at each meal, which is 100% when a subject eats all the food provided and 0% when he/she did not eat any, is calculated from the weight of the food on the plates before and after the meal. Albumin (Alb g/dL), c-reactive protein (CRP mg/dL) and total cholesterol (T-cho mg/dL) are measured before the surgery, one day after the surgery (POD1), 7 days after the surgery (POD7), and when leaving the hospital (ENT).

Body composition is measured using InBody S10 (InBody Japan Inc., Tokyo, Japan), which includes body water balance, hydration percentage (%), total protein (g/dL), total fat (kg), skeletal muscle mass (kg), body cell mass (kg), and basal metabolic rate (kcal/day). The body water balance is the volumetric ratio of the extracellular water to the intracellular water. The hydration percentage is the ratio of the extracellular water amount to the body weight without fat. The measurement is conducted at 7:00 am before breakfast from POD1 to POD7 and at 16: 00 pm before dinner in the preoperative period and from POD8 to POD14.

Progress of rehabilitation is evaluated by treadmills exercise. We assume that the subjects recover the activities of daily living (ADL) when they can conduct treadmills exercise for 20 min.

What are the possible benefits and risks of participating?
Enhanced salt taste using Salt Chip may increase the eating rate, which can be beneficial for fast recovery. Participants may percept too much salt taste, in which case the participants can drop out of the trial immediately.

Where is the study run from?
The study is conducted at Osaki Hospital Tokyo Heart Center.

When is the study starting and how long is it expected to run for?
March 2017 to June 2017.

Who is funding the study?
Keio University provides In-Body. LTaste Inc. provides Salt Chip. The remaining incidental costs are paid by Osaki Hospital Tokyo Heart Center.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
0084CR

Study information

Scientific Title
Effect of dietetic treatment with enhanced salt taste in cardiovascular surgery perioperative period

Acronym
SaltChip

Study objectives
1. Enhanced salt taste promotes eating rate during the perioperative period.
2. Increased eating rate is beneficial in recovery from the surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved, the ethics committee of Osaki Hospital Tokyo Heart Center (5-4-12 Kita-Shinagawa, Shinagawa, Tokyo, 141-0001, Japan; +81-3-5789-8100; +81-3-5789-8101), ref: 0084CR.

Study design
Interventional, nonblinded, parallel trial, single-centre

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Open heart surgery patients

Interventions
The participants in the test group were requested to use Salt Chip®, which can enhance the salt taste without increasing the salt intake amount, at every meal.

The duration of the intervention is from one day before the open heart surgery to ENT.

The eating rate at each meal, which is 100% when a subject eats all the food provided and 0% when he/she did not eat any, was calculated from the weight of the food on the plates before and after the meal. Albumin (Alb g/dL), c-reactive protein (CRP mg/dL) and total cholesterol (T-cho mg/dL) were measured before the surgery, one day after the surgery (POD1), 7 days after the surgery (POD7), and when leaving the hospital (ENT).

Body composition was measured using InBody S10 (InBody Japan Inc., Tokyo, Japan), which included body water balance, hydration percentage (%), total protein (g/dL), total fat (kg), skeletal muscle mass (kg), body cell mass (kg), and basal metabolic rate (kcal/day). The body water balance is the volumetric ratio of the extracellular water to the intracellular water. The hydration percentage is the ratio of the extracellular water amount to the bodyweight without fat. The measurement was conducted at 7:00 am before breakfast from POD1 to POD7 and at 16:00 pm before dinner in the preoperative period and from POD8 to POD14.

Progress of rehabilitation was evaluated by treadmills exercise. We assumed that the subjects recovered the activities of daily living (ADL) when they could conduct treadmills exercise for 20 min.

At approximately 2 weeks the patients who visited the hospital for open-heart surgery during the period were randomised to either the salt chip group or control group. The corresponding period was iterated.

In addition, it was checked if there was any significant differences between the groups in terms of: age, sex, ejection fraction (EF), eating rate before the surgery, Alb, T-cho, body water balance, hydration percentage, total protein, total fat, skeletal muscle mass, body cell mass, and basal metabolic rate (p-value > 0.05).

Intervention Type
Other

Primary outcome measure
The eating rate of the patients during the postoperative period is measured at each meal.

Secondary outcome measures
Progress of rehabilitation was evaluated by treadmills exercise every day. We assumed that the subjects recovered the activities of daily living (ADL) when they could conduct treadmills exercise for 20 min.

Overall study start date

20/12/2016

Completion date
07/07/2017

Eligibility

Key inclusion criteria
Open heart surgery patients

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Unable to give informed consent and/or assent
2. Severe frailty

Date of first enrolment
18/03/2017

Date of final enrolment
19/06/2017

Locations

Countries of recruitment
Japan

Study participating centre
Osaki Hospital Tokyo Heart Center
5-4-12 Kita-Shinagawa, Shinagawa, Tokyo, Japan
Tokyo
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Sponsor information

Organisation
Osaki Hospital Tokyo Heart Center

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Sponsor type
Hospital/treatment centre

Website
http://www.tokyoheart.or.jp/department/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Osaki Hospital Tokyo Heart Center

Funder Name
LTaste Inc.

Funder Name
Keio University

Alternative Name(s)
, , , Keio

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Japan

Results and Publications

Publication and dissemination plan
We are intending to publish the results in archived journal paper in 2019.

Intention to publish date
20/08/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other