# Effects of pectin liquid on gastroesophageal reflux disease in children with cerebral palsy

| Recruitment status No longer recruiting | <ul><li>Prospectively registered</li></ul>            |  |  |
|---|---|--|--|
|   | ☐ Protocol  |  |  |
| Overall study status                    | Statistical analysis plan                             |  |  |
| Completed                               | [X] Results   |  |  |
| Condition category                      | [] Individual participant data                        |  |  |
|   | No longer recruiting  Overall study status  Completed |  |  |

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

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# Additional identifiers

**Protocol serial number** N/A

# Study information

Scientific Title

#### Study objectives

Changing feeding style is an alternative therapy for decreasing GastroEsophageal Reflux (GER) - related symptoms. Use of thickeners is common and effective in decreasing frequent episodes of regurgitation or vomiting in infants, and in improving dysphagia in handicapped patients. We hypothesized that thickener is effective for GastroEsophageal Reflux Disease (GERD) in neurologically impaired children.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

This study was approved by the Human Investigation Committee of Gunma University on 17 February 2005. Informed consent was obtained from the mother of each subject.

#### Study design

Randomized single-blind controlled cross-over multicentre (2 hospitals) study.

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Gastroesophageal Reflux Disease

#### **Interventions**

We enrolled 18 patients (16 male and 2 female) with cerebral palsy from 2 hospitals, Gunma University Hospital and Gunma Rehabilitation Centre for the Physically Handicapped Children. The average age of subjects was  $11.7 \pm 4.4$  years old.

All patients received the enteral formula described below through a naso-gastric tube.

#### Phase 1: pH monitoring

The subjects were randomly allocated to the following 2 groups:

Group A (9 participants): Participants were fed with a high-pectin content diet (enteral formula: pectin liquid = 2:1 [v/v], intervention) and an enteral formula mixed with water added to a similar volume as the pectin liquid (non-pectin diet, control) in a cross-over manner.

Group B (9 participants): Participants were fed with a low-pectin content diet (enteral formula: pectin liquid = 3:1 [v/v], intervention) and a non-pectin diet (control) in a cross-over manner.

Esophageal pH of each participant was monitored over 48 hours while he/she was being fed with the formula described above.

Phase 2: Effects of pectin liquid on GERD symptoms

Group A: Nine patients were fed with a high-pectin content diet for 4 weeks (intervention), and with non-pectin diet (control) for 4 weeks in a cross-over manner.

Group B: Nine patients were fed with a low-pectin content diet for 4 weeks (intervention), and with non-pectin diet (control) for 4 weeks in a cross-over manner.

#### Intervention Type

Drug

#### Phase

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

Pectin

#### Primary outcome(s)

The following were assessed by the esophageal pH monitoring:

- 1. The median values for the % time pH <4 at the lower and upper esophagus
- 2. Number of refluxes per day
- 3. Duration of longest reflux
- 4. Number of refluxes longer than 5 min

#### Key secondary outcome(s))

The following were assessed using the patient's chart filled by the nurse/clinician daily:

- 1. Number of episodes of vomiting per day
- 2. Number of gastric residue with bleeding
- 3. Volume of gastric residue
- 4. Cough score (cough and wheezing)
- 5. Frequency of oxygen use for dyspnea
- 6. Total volume of feeding per day
- 7. Time to return to school

#### Completion date

30/09/2007

# Eligibility

#### Key inclusion criteria

- 1. Cerebral palsy
- 2. Age between 2 to 18

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Child

### Lower age limit

2 years

#### Upper age limit

18 years

#### Sex

All

#### Key exclusion criteria

Patients who received a surgical operation for GERD.

#### Date of first enrolment

01/03/2005

#### Date of final enrolment

30/09/2007

# Locations

# Countries of recruitment

Japan

# Study participating centre

Department of Pediatrics and Developmental Medicine

Gunma Japan

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# Sponsor information

## Organisation

Gunma University, Department of Pediatrics and Developmental Medicine (Japan)

#### **ROR**

https://ror.org/046fm7598

# Funder(s)

## Funder type

University/education

## Funder Name

The Gunma University Graduate School (Japan)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

| Output type     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-----------------|---------|--------------|------------|----------------|-----------------|
| Results article | Results | 16/04/2008   |            | Yes            | No              |