

# The randomised controlled trial to evaluate effectiveness of gargling for the prevention of upper respiratory tract infections

<b>Submission date</b> 26/10/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/11/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/08/2009	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Takashi Kawamura

### Contact details

Yoshida-Honmachi

Sakyo-ku

Kyoto

Japan

606-8501

+81 (0)75 753 2411

kawax@kuhp.kyoto-u.ac.jp

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Acronym

The Great Cold Study 1

## Study objectives

Gargling, especially with gargle medicine, is effective for the prevention of upper respiratory tract infections (URTIs).

The follow-up period is 60 days.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised open label controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Prevention

## Participant information sheet

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

Upper respiratory tract infections

## Interventions

Gargling with tap water, gargling with diluted povidone-iodine, and usual care

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome measure

Incidence of upper respiratory track infections (URTI).

**Secondary outcome measures**

Severity of upper respiratory track infections (URTI).

**Overall study start date**

01/11/2002

**Completion date**

30/04/2003

## **Eligibility**

**Key inclusion criteria**

Healthy volunteers aged 18-65 years

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

300

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/11/2002

**Date of final enrolment**

30/04/2003

## **Locations**

**Countries of recruitment**

Japan

**Study participating centre**  
**Yoshida-Honmachi**  
Kyoto  
Japan  
606-8501

## **Sponsor information**

**Organisation**  
Kyoto University (Japan)

**Sponsor details**  
Yoshida-Honmachi  
Sakyo-ku  
Kyoto  
Japan  
606-8501  
+81 (0)75 753 7531  
info@mail.adm.kyoto-u.ac.jp

**Sponsor type**  
University/education

**ROR**  
<https://ror.org/02kpeqv85>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
Uehara Memorial Foundation (Japan)

**Funder Name**  
Suzuken Memorial Foundation (Japan)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date

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?
<a href="#">Results article</a>	results	01/11/2005		Yes	No
<a href="#">Results article</a>	results	01/11/2007		Yes	No
<a href="#">Results article</a>	results	16/12/2008		Yes	No