ISRCTN67680497 https://doi.org/10.1186/ISRCTN67680497

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

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|---|---|---|
| **Submission date**<br>26/10/2004 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>03/11/2004 | **Overall study status**<br>Completed | |
| **Last Edited**<br>24/08/2009 | **Condition category**<br>Respiratory | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## 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

### Study type(s)
Prevention

### 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(s)
Incidence of upper respiratory track infections (URTI).

### Key secondary outcome(s))
Severity of upper respiratory track infections (URTI).

### Completion date
30/04/2003

## Eligibility

### Key inclusion criteria
Healthy volunteers aged 18-65 years

### Participant type(s)
Healthy volunteer

### Healthy volunteers allowed

No

**Age group**
Adult

**Lower age limit**
18 years

**Upper age limit**
65 years

**Sex**
All

**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)

**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

## 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 | 01/11/2005 | | Yes | No |
| Results article | results | 01/11/2007 | | Yes | No |
| Results article | results | 16/12/2008 | | Yes | No |