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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

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