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

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

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