

The effect of intranasal sodium cromoglycate on symptoms of suspected acute viral upper respiratory tract infection (URTI) in children

Submission date 23/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/09/2007	Condition category 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

Dr Christopher C Butler

Contact details

Department of General Practice
University of Wales College of Medicine Health Centre Maelfa
Llanedeyrn
Cardiff
United Kingdom
CF23 9PN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G9900236

Study information

Scientific Title

Acronym

SAVIT Study

Study objectives

The trial is designed to answer the question; "In children presenting in general practice with suspected acute viral upper respiratory tract infection of less than 36 h duration, does treatment with intranasal sodium cromoglycate improve symptoms more than placebo?"

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Primary care

Interventions

300 children will be randomised to receive either normal saline nose spray or sodium cromoglycate 4% nose spray every 2 h (during waking hours) for the first 2 days, and every 4 h for a further 5 days or until quite well.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

CARIFS Scale Score

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/1999

Completion date

31/08/2000

Eligibility

Key inclusion criteria

Children aged from 6 months to 6 years with suspected acute viral URTI for less than 36 h

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

300

Key exclusion criteria

Children with: a history of having taken cromolyns or steroids within the previous week; carers who are incapable of giving informed consent or unable to keep symptom diaries; an established complication requiring immediate hospitalisation, or for whom the clinician plans to prescribe antibiotics at the first consultation.

Date of first enrolment

01/09/1999

Date of final enrolment

31/08/2000

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre
Department of General Practice
Cardiff
United Kingdom
CF23 9PN

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.uk>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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:	22/06/2002		Yes	No