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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
23/10/2000		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/10/2000	Completed	[X] Results		
<b>Last Edited</b> 13/09/2007	Condition category Respiratory	[] 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

Protocol serial number 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

#### Study type(s)

**Not Specified** 

### 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(s)

**CARIFS Scale Score** 

#### Key secondary outcome(s))

Not provided at time of registration

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### 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)

# 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**

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