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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/10/2000	**Overall study status** Completed	
Last Edited 13/09/2007	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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