



Bromhexine and topical nasal decongestants for cough and colds in children

Efficacy information- part

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Bromhexine

- Mucolytic
 - For conditions with abnormal mucus secretion and impaired mucus transport (breaks up the phlegm)
- Boehringer
 - 28 studies, 1441 exposures
 - Mixed conditions – including asthma, pneumonias
 - Mixed formulations – in 9 studies no longer available
 - Small studies – 25 of the studies had less than 55 participants

Bromhexine

- RCT – Tarantino et al (1988)
 - 3 to 12 years old
 - 8 days treatment
 - N = 30 (15 in each arm)
 - Acute sinus inflammation (included whooping cough, measles complications etc)
 - All patients received amoxicillin
 - Used 5- Likert scale for nasal secretions, rhinitis score
 - Outcome statistically favored bromhexine – but
 - baseline characteristics did not appear balanced (baseline pain = 2/15 in bromhexine group; 5/15 in placebo)
 - Effect most evident at day 4 to 6 (? Slow onset of

Bromhexine

- Van Bever et al (1987)
 - Asthma
 - 3 to 14 year old
 - Two weeks, nebulised
 - NSD compared to saline
- Stewart et al (1985)
 - OME
 - 3 to 8 year olds (n = 95; 190 ears; 380 treatments)
 - Four week courses
 - NSD compared to placebo
- Ambroxol (metabolite)
 - Cystic fibrosis, paediatric, AOM, respiratory distress syndrome

Mucolytic - letostein

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- Acute febrile bronchitis, N=40. lower cough score in active treatment group cf placebo. (Nespoli et al 1989).

Topical nasal decongestants

- Xylometazoline (Otrivine[®])
- Oxymetazoline
- Phenylephrine
- Ipratropium (Atrovent[®])

Xylometazoline

- 4 x RCTs
 - 2 positive
 - 10 to 75 years, for allergic rhinitis and included sodium cromoglycate. *Fradis et al. (1987)*
 - 12 to 75 years for tympanic membrane perforation. *Jensen et al. (1990)*
 - 2 NSD
 - Both had adjunctive amoxicillin and were for chronic maxillary sinusitis *Otten & Grote (1988) (1990)*
- 8 studies but no placebos

Xylometazoline

- Michel et al (2005)
 - Rhinosinusitis
 - Mineral salts (n = 66) vs xylometazoline (n = 66)
 - 2 to 6 year olds
 - 14 days treatment
 - NSD (both groups improved by 2 weeks; mineral salts better at 1 week)
- Van Heerbeek et al (2002)
 - OME and ventilation tubes
 - N = 80
 - NDS on ventilatory or the protective function of the Eustachian tube)

Phenylephrine

- Turner & Darden (1996)
 - Common cold – measuring middle ear pressure
 - 6 to 18 months old
 - Treatment of nasal obstruction with topical adrenergic decongestants does not improve abnormal middle ear pressures during the common cold

Cochrane reviews

Acute respiratory infections

- Summary of Clinical trials in Children
 - Mucolytics
 - Bromhexine 0
 - Letostein 1
 - Acute febrile bronchitis, N=40. lower cough score in active treatment group cf placebo. (Nespoli et al 1989).
 - Topical nasal decongestants
 - Imidazoline, anticholinergics 0

Bromhexine and topical nasal decongestants

- A paucity of good clinical trials
- A paucity of evidence of efficacy