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[Intervention Review]

Cyclamen europaeum extract for acute sinusitis

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ABSTRACT

Background

Acute sinusitis is a common reason for primary care encounters. It causes significant symptoms including facial pain, congested nose, headache, thick nasal mucus, fever, and cough and often results in time off work or school. Sinusitis treatment focuses on eliminating causative factors and controlling the inflammatory and infectious components. The frozen, dried, natural fluid extract of the *Cyclamen europaeum* plant delivered intranasally is thought to have beneficial effects in relieving congestion by facilitating nasal drainage, and has an anti-inflammatory effect.

Objectives

To assess the effectiveness of topical intranasal Cyclamen europaeum extract on clinical response in adults and children with acute sinusitis.

Search methods

We searched CENTRAL, which includes the Cochrane Acute Respiratory Infections Group's Specialised Register, MEDLINE, Embase, and trials registers (ClinicalTrials.gov; WHO ICTRP) in January 2018. We also searched the reference lists of included studies and review literature for further relevant studies and contacted trial authors for additional information.

Selection criteria

Randomised controlled trials comparing *Cyclamen europaeum* extract administered intranasally to placebo, antibiotics, intranasal corticosteroids, or no treatment in adults or children, or both, with acute sinusitis. Acute sinusitis was defined by clinical diagnosis and confirmed by nasal endoscopy or by radiological evidence.

Data collection and analysis

Two review authors independently extracted data and assessed trial quality. We used standard methodological procedures expected by Cochrane.

Main results

We included two randomised controlled trials that involved a total of 147 adult outpatients with acute sinusitis confirmed by radiology or nasal endoscopy who were assigned to *Cyclamen europaeum* nasal spray or placebo study arms for up to 15 days. The risk of selection and detection bias was unclear, as allocation concealment and blinding of outcome assessors were not reported in either study. Attrition was high (60%) in one study, although dropouts were balanced between study arms.

Neither study reported our two primary outcomes: proportion of participants whose symptoms resolved or improved at 14 days and 30 days. No serious adverse events or complications related to treatment were reported; however, more mild adverse events such as nasal

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and throat irritation, mild epistaxis, and sneezing occurred in *Cyclamen europaeum* group participants (50%) compared to placebo group participants (24%) (risk ratio 2.11, 95% confidence interval 1.35 to 3.29); moderate-quality evidence.

Authors' conclusions

The effectiveness of *Cyclamen europaeum* for people with acute sinusitis is unknown. Although no serious side effects were observed, 50% of participants who received *Cyclamen europaeum* reported adverse events compared with 24% of those who received placebo.

PLAIN LANGUAGE SUMMARY

Is Cyclamen europaeum extract effective for people with acute sinusitis?

Review question

We assessed the effectiveness of *Cyclamen europaeum* frozen, dried, natural fluid extract, an herbal medicine from the tuber of *Cyclamen europaeum*, given as a nasal spray compared with sham treatment (placebo) to resolve or improve acute sinusitis in adults and children.

Background

Acute sinusitis is a common condition that occurs when the bone cavities in the vicinity of the nose become inflamed from infection. Symptoms can include thick nasal mucus, congested nose, facial pain, headache, fever, and cough. Symptoms last up to eight weeks in adults and up to 12 weeks in children. Acute sinusitis is most often caused by viruses; complications can occur if the infection spreads. Acute sinusitis is a common condition that imposes significant costs.

A range of conservative treatments are available to treat acute sinusitis. Antibiotics are commonly prescribed, but clinical guidelines disagree about when antibiotics should be given to treat acute sinusitis. The few studies on *Cyclamen europaeum* extract given as nasal spray suggest that it may help by relieving nasal congestion.

Search date

The evidence is current to 18 January 2018.

Study characteristics

We included two studies involving 147 adults with acute sinusitis. Participants were randomly allocated to receive *Cyclamen europaeum* delivered as an intranasal spray or a non-active substance for up to 15 days.

Study funding sources

Pharmaceutical companies funded both studies.

Key results

We wanted to find out the proportion of participants whose symptoms resolved or improved up to 14 days and 30 days, but did not find any evidence. The included studies provided data for changes in symptom scores for acute sinusitis with treatment. One study reported improvement in facial pain up to seven days. Neither study reported complications or days off school or work.

People who received *Cyclamen europaeum* rather than a non-active substance reported more side effects like nasal irritation, sneezing, and mild nasal bleeding. No major side effects occurred.

We found no evidence as to whether Cyclamen europaeum is effective or not.

Quality of the evidence

We assessed the quality of both studies and judged the evidence to be moderately reliable for the only outcome that could be assessed, that is side effects. One study had a high dropout rate (60%), but dropouts were described and balanced between study arms. We found consistent results between studies for adverse events. Neither study reported whether the outcomes assessors knew which treatments the participants received. Due to the small number of participants and weaknesses in study design, we cannot be sure of the result.