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Clinical Trial > Headache. 2005 Mar;45(3):196-203. doi: 10.1111/j.1526-4610.2005.05044.x.

# Migraine prevention in children and adolescents: results of an open study with a special butterbur root extract

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### **Abstract**

**Objective:** To explore the role of a special butterbur root extract for migraine prevention in children and adolescents with severe migraines.

**Background:** Two randomized and placebo-controlled trials with a total of 289 migraine patients have demonstrated the efficacy and safety of a special butterbur root extract in the reduction of migraine attacks in adults. We studied whether butterbur had the potential as an efficient and well-tolerated migraine preventive in children and adolescents.

**Design/methods:** 108 children and adolescents between the ages of 6 and 17 were included in a multicenter prospective open-label study. Participants suffered from migraines diagnosed according to IHS classifications for at least 1 year. Patients were treated with 50 to 150 mg of the butterbur root extract depending on age for a period of 4 months. Treatment progression was recorded in migraine journals especially designed for children and adolescents.

**Results:** 77% of all patients reported a reduction in the frequency of migraine attacks of at least 50%. Attack frequency was reduced by 63%. 91% of patients felt substantially or at least slightly improved after 4 months of treatment. About 90% of each, doctors and patients, reported well-being or even improved well-being. Undesired effects (7.4%) included mostly eructation. No serious adverse events occurred and no adverse event caused a premature termination.

**Conclusions:** The results and low rate of adverse events in this open prospective migraine prevention study in children and adolescents are similar to the results of two multicenter placebocontrolled butterbur studies in adults. Butterbur root extract shows a potential as an effective and well-tolerated migraine prophylaxis also for children and teenagers.

### Comment in

Clinical trial ethics.

Fox AW.

Headache. 2005 Sep;45(8):1090-1; author reply 1091. doi: 10.1111/j.1526-4610.2005.05195\_3.x.

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