

Child and Adolescent Migraine Prevention (CHAMP)

Brief Summary Report

Thank you!

Thank you for volunteering your time and effort to CHAMP. We sincerely appreciate your contribution to this trial in helping to advance medical knowledge.

At a glance.

Our goal:

To test amitriptyline and topiramate to see if they can reduce the number of days that children and teenagers diagnosed with migraines (age 8-17 years) have headaches. The medications were compared to each other and a placebo (a fake pill with no medication in it).

Participants:

Approximately 350 kids, aged 8-17 years.

Side effects:

Most were mild (e.g., feeling tired); a few people had serious side effects.

Results:

Neither of the two medications were better than the placebo. The trial was stopped because it became clear that neither medication was reducing the number of headaches.

Next steps:

Further research on other pediatric migraine treatment options is necessary.



Trial information.

Trial Name: The Child and Adolescent Migraine Prevention (CHAMP) Trial

Investigator(s): Scott W. Powers, PhD; Andrew D. Hershey, MD, PhD; Christopher S. Coffey, PhD

Sponsor: Children's Hospital Medical Center, Cincinnati

Funder: National Institutes of Health (NIH)

Study Start and Completion Dates: June 2012 – January 2016

Clinicaltrials.gov number: [NCT01581281](https://clinicaltrials.gov/ct2/show/study/NCT01581281)

For more information:

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A scientific paper on the trial is [here](#). More information is found [here](#).



About the trial.

What did we do?

We compared two medications (called amitriptyline* and topiramate**) and a placebo (a pill with no medication in it that looked the same as two medications).

*Typical amount of amitriptyline was ~1 milligram per kilogram of body weight per day.

**Typical amount of topiramate was ~2 milligram per kilogram of body weight per day.

How did we do it?

All participants counted how many days they had headaches over a period of 28 days at the start of the trial. Then, they were divided into groups by random chance to decide if they would receive amitriptyline, topiramate, or the placebo for the next 24 weeks to see how the number of headaches might change.

What did we want to know?

- 1) If people who took amitriptyline had fewer days with headaches than people who took the placebo.
- 2) If people who took topiramate had fewer days with headaches than people who took the placebo.
- 3) If one of the two medications worked better than the other to reduce headaches.

Study phase:



*Phase 3: This phase focuses on whether the drug works well and how safe it is. In this trial, it involves comparing two different medications (topiramate & amitriptyline) and a placebo.

*For more details about what other phases are, please see [link](#).



Participants.

Who could participate in the trial (known as inclusion/exclusion criteria):

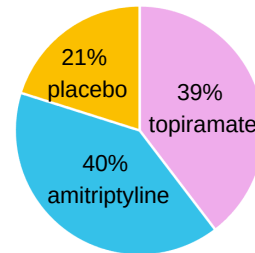
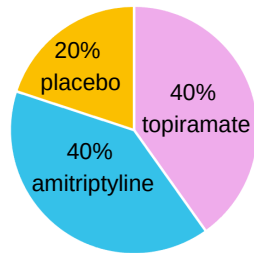
Youth ages 8-17 years, diagnosed with migraine (with or without aura), based on established medical criteria.

The full list of inclusion/exclusion criteria can be accessed [here](#).

Number of participants:

Trial participants who **started** the study (n = 361)

Trial participants who **completed** the trial (n = 328)

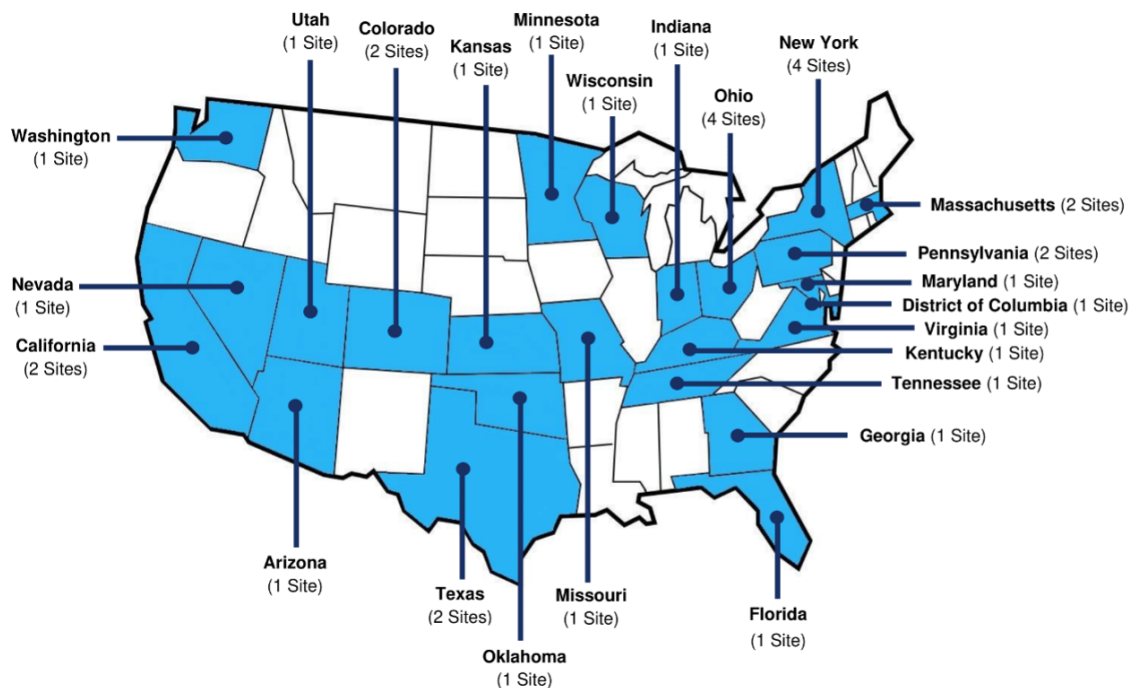


- 145 participants (40%) started the study in the Topiramate group
- 144 participants (40%) started the study in the Amitriptyline group
- 72 (20%) participants started the study in the Placebo group
- 130 participants (39%) took Topiramate and completed the study
- 132 participants (40%) took Amitriptyline and completed the study
- 66 participants (21%) took Placebo and completed the study



Location.

Participants were enrolled from 31 sites in the United States from a total of 35 study locations. For specific study sites, please visit this [site](#).





Results.

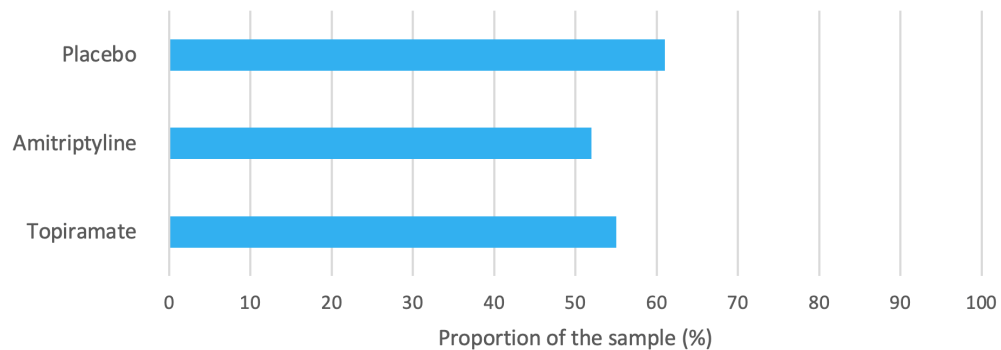
Only combined results are described (to protect privacy); individual results are not provided.

- Neither amitriptyline nor topiramate were found to be better for treating migraine headache than the placebo.
- Children and adolescents receiving amitriptyline or topiramate showed more side effects than those who took the placebo.

Proportion of the sample whose number of days with headache* were reduced by at least half:

This was very similar among the three groups, meaning that all 3 arms had a good reduction of headaches with over half of the sample having a 50% or greater reduction, but **neither medication worked better than placebo.**

Proportion of participants whose number of days with headache reduced by at least half

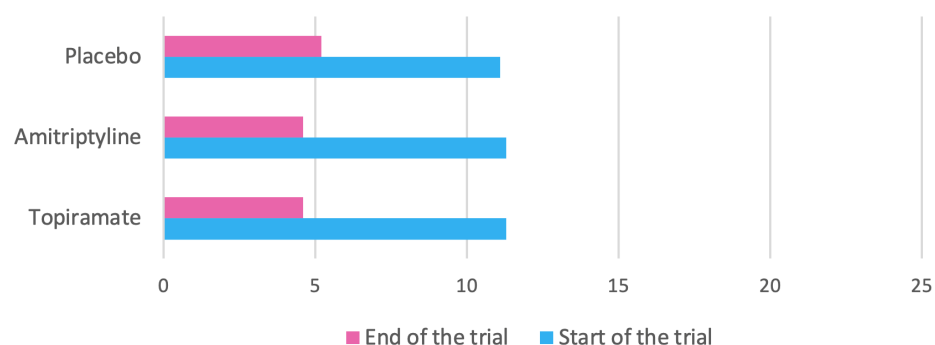


*Headache day = A 24-hour period starting at midnight in which a headache happened. We compared how many days participants had headaches over a period of 28 days at the start of the trial (before starting medication or placebo) to the number of days they had headaches during the last 28 days of the trial.

Changes in number of headache days in a 28-day period:

This was very similar among the three groups, meaning that **neither medication worked better than placebo.**

Changes in Number of Headache Days Over a 28-day Period





Results (continued).

Improvement in headache score measured by a questionnaire called the PedMIDAS* Scale

All three groups showed improvement tracked by this questionnaire that was very similar, as the average score changed from “moderate” to “mild” disability in each group. This means that **neither medication worked better than placebo.**

	Topiramate	Amitriptyline	Placebo
PedMIDAS score at start of trial	41.2 (moderate disability)	41.3 (moderate disability)	42.0 (moderate disability)
PedMIDAS score at end of trial	14.4 (mild disability)	18.8 (mild disability)	19.4 (mild disability)
Difference between PedMIDAS score at the start and end of study	26.8	22.5	22.6

* PedMIDAS Scale was completed by children and teenagers to track how headaches and migraines affect different aspects of their lives (e.g., school, home, play, and social activities).

How well did the participants tolerate the medication?

There was no significant difference in how well the participants in the different groups tolerated the medication. More people taking topiramate or amitriptyline quit the trial due to side effects, compared to those taking the placebo.

	Topiramate	Amitriptyline	Placebo
Number of participants who withdrew from trial due to side effects	8	7	1



Side effects.

People who took amitriptyline or topiramate more commonly had **mild side effects** than the people who took placebo. **A few people had serious side effects.** In the table below, we have listed the top 3 most frequently reported side effects for amitriptyline and topiramate.

A complete list of all mild and serious side effects experienced may be found [here](#).

Side Effect	Frequency				Severity			Long Term Impact	
	Very Likely (> 75%)	Likely (50-75%)	Less Likely (5-50%)	Rare (<5%)	Mild	Moderate	Severe	Temporary	Permanent
Amitriptyline									
Feeling tired			x		x			x	
Dry mouth			x		x			x	
Cognitive disorder			x		x			x	
Topiramate									
Tingling sensation in arms and legs			x		x			x	
Feeling tired			x		x			x	
Memory impairment			x		x			x	



Trial conclusions.

The trial was stopped earlier than planned because it was obvious that amitriptyline and topiramate were not working to help treat headaches. It is very unlikely that if the trial had continued with a larger number of participants that a different result would have been found.



Next steps.

The trial was stopped for the reasons above and there was no interest in extending this trial. Future research on other pediatric migraine treatment options is necessary.

Discussing this trial with your doctor:

If you wish, you may let your child's doctor know that this trial showed no evidence of a benefit, and was stopped early for this reason. Both medications caused side effects.