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Completed

An Open-labeled Trial of Ramipril in Patients With Migraine

ClinicalTrials.gov ID NCT01402479

Sponsor Seoul National University Hospital

Information provided by Seoul National University Hospital

Last Update Posted 2011-08-08

Study Details Tab

Study Overview

Brief Summary

Physiology of migraine involving renin-angiotensin systems (RAS) has been implicated. Ramipril is a broadly-used angiotensin-converting enzyme inhibitor. The investigators attempt to test the efficacy of ramipril on the prophylaxis of migraine attacks.

Official Title

An Open-labeled Trial of Ramipril in Patients With Migraine

Feedback

Conditions ⓘ

Migraine With Hypertension

Intervention / Treatment ⓘ

- Drug: Ramipril

Other Study ID Numbers ⓘ

Study Start ⓘ

2004-10

Primary Completion (Actual) ⓘ

2005-07

Study Completion (Actual) ⓘ

2005-07

Enrollment (Actual) ⓘ

50

Study Type ⓘ

Interventional

Phase ⓘ

Phase 2

Resource links provided by the National Library of Medicine

[MedlinePlus Genetics](https://medlineplus.gov/genetics/) (https://medlineplus.gov/genetics/) related topics:
[Migraine](https://medlineplus.gov/genetics/condition/migraine) (https://medlineplus.gov/genetics/condition/migraine).
[Hypertension](https://medlineplus.gov/genetics/condition/hypertension) (https://medlineplus.gov/genetics/condition/hypertension).

[MedlinePlus](https://medlineplus.gov/) (https://medlineplus.gov/) related topics:
[Migraine](https://medlineplus.gov/migraine.html) (https://medlineplus.gov/migraine.html).

[Drug Information](https://dailymed.nlm.nih.gov/dailymed/) (https://dailymed.nlm.nih.gov/dailymed/) available for:
[Ramipril](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Ramipril) (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Ramipril).

[FDA Drug and Device Resources](https://clinicaltrials.gov/fda-links) (<https://clinicaltrials.gov/fda-links>).

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations) (<https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations>).

This study has 1 location

Korea, Republic of



Seoul, Korea, Republic of, 110-744

Seoul National University Hospital

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](https://clinicaltrials.gov/study-basics/learn-about-studies) (<https://clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Inclusion Criteria:

- Patients with chronic migraine are included in this study. Migraineurs should be aged 20 to 70 years old with the ability to read and understand the self-report scales, including the headache diary, used in this study.

Exclusion Criteria:

1. Medication overuse headache are excluded in this study.
2. Treatment with other ACEI or medication that may affect ARS
3. Treatment with migraine prophylactic medications or anti-hypertensive agents including β adrenergic receptor or calcium channel blockers
4. Past history of hepatic or renal dysfunction; an abnormal electrocardiography; a psychiatric disorder; a history of substance abuse; pregnancy or lactation; use of anti-psychotics, antidepressants, or anti-anxiety drugs.

Ages Eligible for Study ⓘ

20 Years to 70 Years (Adult, Older Adult)

Sexes Eligible for Study ⓘ

All

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

- Primary Purpose ⓘ** : Treatment
- Allocation ⓘ** : Non-Randomized
- Interventional Model ⓘ** : Single Group Assignment
- Masking ⓘ** : None (Open Label)

Arms and Interventions

| Participant Group/Arm i | Intervention/Treatment i |
|--|---|
| Active Comparator: ramipril open label single arm trial | Drug: Ramipril <ul style="list-style-type: none">ramipril 2.5mg twice a day |

What is the study measuring?

Primary Outcome Measures i

| Outcome Measure | Measure Description | Time Frame |
|--------------------|---------------------|------------|
| headache frequency | headache days | 12 week |

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor i

Seoul National University Hospital

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

| |
|--|
| First Submitted ⓘ |
| 2011-07-24 |
| First Submitted that Met QC Criteria ⓘ |
| 2011-07-24 |
| First Posted (Estimated) ⓘ |
| 2011-07-26 |

Study Record Updates

| |
|--|
| Last Update Submitted that met QC Criteria ⓘ |
| 2011-08-05 |
| Last Update Posted (Estimated) ⓘ |
| 2011-08-08 |
| Last Verified ⓘ |
| 2011-07 |

More Information

Terms related to this study

| |
|---|
| Keywords Provided by Seoul National University Hospital |
| migraine, ramipril, hypertension |
| Additional Relevant MeSH Terms |
| Vascular Diseases |
| Cardiovascular Diseases |
| Headache Disorders, Primary |
| Headache Disorders |
| Brain Diseases |
| Central Nervous System Diseases |
| Nervous System Diseases |
| Migraine Disorders |

Hypertension

Angiotensin-Converting Enzyme Inhibitors

Protease Inhibitors

Enzyme Inhibitors

Molecular Mechanisms of Pharmacological Action

Antihypertensive Agents

Ramipril