COMPLETED

Homocysteine After Nitrous Oxide Anesthesia

ClinicalTrials.gov ID NCT00482456

Sponsor Medical University of Vienna

Information provided by Medical University of Vienna

Last Update Posted 2007-06-05

Study Details Tab

Study Overview

Brief Summary

Our study looks at the interaction of a common muta e MTHFR gene and the risk of developing higher homocysteine levels after nitrous oxide (N2O) anesthesia.

Specifically, we want to test the hypothesis that healthy patients carrying the MTHFR 677C>T

Detailed Description

Nitrous oxide - laughing gas - is a widely used anaesthetic gas with many favourable but also some dangerous properties. Among the latter is the increase in homocysteine levels after nitrous oxide (N2O) exposure by inhibition of enzymes in the vitamin B12 pathway. Elevated homocysteine levels have been found to be an independent risk factor for ischemic events and are associated with an increased risk for perioperative myocardial ischemia. If a patient carries one or more loss-of-function mutations in enzymes of the methionine/homocysteine/folate pathway he is at an increased risk for hyperhomocysteinemia and if exposed to N2O might suffer severe, sometimes disastrous neurological damage. Recently, a case report in the New England Journal of Medicine reported the death of a child with an enzyme defect in the MTHFR gene after anaesthesia with nitrous oxide (NEJM 2003;349:45-50).

Thus, we are convinced that if we can determine the risk of patients who carry mutations in the MTHFR gene and undergo anaesthesia with N2O for developing pathological levels of homocysteine, we can add an important piece of information to the safety profile of N2O.

Our study tests the hypothesis that patients who carry the 677C<T mutation in the MTHFR gene (the most common mutation) have a higher risk of developing hyperhomocysteinemia

Official Title

Influence of the MTHFR 677C>T Mutation on Homocysteine Levels After Nitrous Oxide Anesthesia.

Conditions

Anesthesia, General | Adverse Effects | Nitrous Oxide

Intervention / Treatment

- Drug: Nitrous oxide

Other Study ID Numbers

- EK 286/2004

Study Start

2005-01

Primary Completion

Study Completion (Actual)

2007-03

Enrollment (Actual)

140

Study Type

Interventional

Phase

Phase 4

Resource links provided by the National Library of Medicine

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for: Nitrous oxide (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Nitrous+oxide)

Other U.S. FDA Resources (https://classic.clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Austria

Vienna, Austria, A-1090
Dept of Anesthesiology, Medical University of Vienna

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).

Eligibility Criteria

Description

Inclusion Criteria:

- Patient scheduled for general anaesthesia (> 2 hours)
- Age > 18 years
- ASA status I-II

Exclusion Criteria:

- Pregnancy
- Age < 18 years
- contraindication against N2O: pneumothorax, mechanical bowel obstruction, middle ear occlusion, laparoscopic surgery

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

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?

What is the study measuring?

Primary Outcome Measures

Outcome Measure
Measure Description
Time Frame
Outcome Measure Homocysteine levels dependent on MTHFR genotype
Measure Description
Time Frame 2 years

Collaborators and Investigators

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

Sponsor

Medical University of Vienna

Collaborators

No information provided

Investigators

- Principal Investigator: Peter Nagele, M.D., Medical University of Vienna

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

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

2007-06-01

First Submitted that Met QC Criteria

2007-06-01

First Posted (Estimated)

2007-06-05

Study Record Updates

Last Update Submitted that met QC Criteria

2007-06-01

Last Update Posted (Estimated)

2007-06-05

Last Verified

2007-05

More Information

Terms related to this study

Keywords Provided by Medical University of Vienna

Nitrous oxide
Homocysteine
folate
vitamin B12

Additional Relevant MeSH Terms

Anesthetics, Inhalation
Anesthetics, General
Anesthetics
Central Nervous System Depressants
Physiological Effects of Drugs
Analgesics, Non-Narcotic
Analgesics
Sensory System Agents
Peripheral Nervous System Agents
Nitrous Oxide

Study Documents

No study documents available