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Metabolic Effects of Alcohol

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators.
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ClinicalTrials.gov Identifier: NCT00167115

Recruitment Status : Completed
First Posted : September 14, 2005
Last Update Posted : July 10, 2012

View this study on Beta.ClinicalTrials.gov

Sponsor:
Bantle, John P., MD

Information provided by (Responsible Party):
University of Minnesota (Bantle, John P., MD)

Study Description

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Brief Summary:

The hypotheses to be tested are 1) the use of alcohol in the form of wine with the evening meal will lower plasma glucose during the night and result in lower fasting plasma glucose the next morning; 2) the chronic use of alcohol in moderation in the form of wine will have beneficial effects on plasma lipids in type 2 diabetic subjects.

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Condition or disease	Intervention/treatment	Phase
Type 2 Diabetes Mellitus	Drug: Alcohol	Not Applicable

Detailed Description:

The use of alcohol in moderation has been associated with reduced mortality rates, reduced risk of cardiovascular disease and reduced risk for type 2 diabetes. However, the effects of alcohol in persons with type 2 diabetes have not yet been defined. Moreover, the possibility of alcohol induced hypoglycemia remains a safety concern. Finally, little is known about the effects of alcohol on plasma lipids in people with diabetes. To address these issues, two substudies are proposed. The first substudy will examine the acute effects of alcohol in the form of wine at supper on postprandial and nocturnal glucose levels. The second substudy will examine the effects of alcohol in the form of wine consumed regularly for one month on plasma lipids.

To test these hypotheses, 20 type 2 diabetics will be studied. In substudy 1, subjects will be admitted to the Clinical Research Center for a two day inpatient stay. Blood samples for plasma glucose and serum insulin will be obtained every two hours from 5:00 pm to 7:00 am. On one day, subjects will recieve 8 ounces of wine with dinner. On the other day, subjects will recieve 8 ounces of fruit juice with dinner. The primary endpoint of substudy 1 will be fasting plasma glucose. In substudy 2, subjects will be asked to consume 4-8 ounces of wine in the evening for one month and to abstain from wine and alcohol containing beverages for one month. Fasting blood samples will be obtained after the month of wine consumption and after the month of abstention from alcohol for measurement of fasting lipids. The primary endpoint of substudy 2 will be fasting HDL cholesterol.

Study Design

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Study Type :	Interventional (Clinical Trial)
Enrollment :	20 participants
Allocation:	Randomized
Intervention Model:	Crossover Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Metabolic Effects of Alcohol in the Form of Wine in Persons With Type 2 Diabetes Mellitus
Study Start Date :	December 2004
Actual Primary Completion Date :	September 2005
Actual Study Completion Date :	September 2005

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: Type 2 diabetes

Drug Information available for: Ethanol

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U.S. FDA Resources

Arms and Interventions

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Outcome Measures

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Primary Outcome Measures :

1. Fasing plasma glucose
2. Fasting plasma HDL cholesterol

Secondary Outcome Measures :

1. Episodes of hypoglycemia

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	40 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

Type 2 diabetes HbA1c 6.0-8.0% age > 40 years

Exclusion Criteria:

History of alcoholism or alcohol abuse liver disease blood pressure > 150/90

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT00167115***

Locations

United States, Minnesota

University of Minnesota
Minneapolis, Minnesota, United States, 55455

Sponsors and Collaborators

Bantle, John P., MD

Investigators

Principal Investigator: John Bantle, MD University of Minnesota

More Information

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Responsible Party:	Bantle, John P., MD
ClinicalTrials.gov Identifier:	NCT00167115 History of Changes
Other Study ID Numbers:	0406M61001 Bantle1
First Posted:	September 14, 2005 Key Record Dates
Last Update Posted:	July 10, 2012
Last Verified:	July 2012

Keywords provided by University of Minnesota (Bantle, John P., MD):

Alcohol
Type 2 diabetes mellitus
Plama glucose
HDL cholesterol

Additional relevant MeSH terms:

Diabetes Mellitus

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Diabetes Mellitus, Type 2
Glucose Metabolism Disorders
Metabolic Diseases
Endocrine System Diseases

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