The effect of vitamin D supplementation on serum hepatic enzymes, oxidative stress indicators & inflammatory markers in patients with Non-Alcoholic Fatty Liver Disease: A Randomized Controlled trial

Protocol summary

Summary
The aim of study is evaluation of the effect of vitamin D supplementation on serum hepatic enzymes, oxidative stress indicators & inflammatory markers in patients with Non-Alcoholic Fatty Liver Disease. Study design is double blind placebo controlled randomized clinical trial. The study sample includes 60 patients (30 in intervention and 30 in control group) diagnosed with non alcoholic fatty liver disease of both gender. Inclusion Criteria: diagnosis to have non alcoholic fatty liver disease ages above 18 and serum alanine transaminase enzyme level higher than normal (> 40 U/L). Exclusion criteria: Alcohol consumption greater than 20 g per day, pregnancy, lactation, having other hepatic diseases, using hepatotoxic drugs and consumption of vitamin D, vitamin E and calcium supplementation during last 6 months. Intervention: One pearl of vitamin D supplement contains 50000 IU vitamin D will be prescribed every other week for 4 months in intervention group. One placebo contains edible paraffin will be prescribed every other week for 4 months in control group. Primary Outcomes: Serum levels of hepatic enzymes include Alanine transaminase, Aspartate transaminase and alkaline phosphatase. Secondary Outcomes: Insulin resistance, Tumor necrosis factor α, Transforming growth factor β, hs-CRP, Adiponectin, Total antioxidant capacity, Malondialdehyde, Cytokeratin-18, Lipid profile, serum level of vitamin D.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2012071810333N1
Registration date: 2012-11-14, 1391/08/24
Registration timing: prospective

Last update:
Update count: 0
Registration date
2012-11-14, 1391/08/24

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Recruitment status
Recruitment complete
Funding source
Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date
2012-11-21, 1391/09/01
Expected recruitment end date
2013-11-22, 1392/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of vitamin D supplementation on serum hepatic enzymes, oxidative stress indicators & inflammatory markers in patients with Non-Alcoholic Fatty Liver Disease: A Randomized Controlled trial

Public title
The effect of vitamin D supplementation in Non Alcoholic
Fatty Liver Disease treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Diagnosis to have non alcoholic fatty liver disease confirmed with sonography result, ages above 18 and serum alanine transaminase enzyme level higher than normal (> 40 U/L). Diabetic patients will include who have been recently diagnosed with diabetes and not using blood glucose lowering drugs or if they consume insulin and metformin, it would pass at least 6 months from starting the treatment and during this period the dose of metformin and insulin are not changed. Exclusion criteria: Alcohol consumption greater than 20 g per day, pregnancy, lactation, diseases such as hereditary hemochromatosis, Wilson’s disease, an enzyme deficiency α1 Antitripsin, history of jejunoileal bypass surgery orgastroplasty, experience to perform the total parenteral nutrition at 6 months before, consumption of hepatotoxic drugs such as calcium channel blocker, high doses of synthetic estrogens, methotrexate, amiodarone, chloroquine, a history of hypothyroidism and Cushing’s syndrome. Serum calcium greater than 10.6mg / dl , a history of kidney stones, renal failure, intake of vitamin D, vitamin E and calcium supplements during last 6 months.

Age
From 18 years old to 75 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ahvaz Jundishapur University of Medical Sciences
Street address
Deputy of research and technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Ave, Ahvaz, Iran
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Approval date
2012-10-27, 1391/08/06

Ethics committee reference number
ETH-605

Health conditions studied

1
Description of health condition studied
non alcoholic fatty liver disease

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver

Primary outcomes

1
Description
Alanine Transaminase

Timepoint
Before and after intervention

Method of measurement
U/L - Laboratory kit

2
Description
Aspartate transaminase

Timepoint
Before and after intervention

Method of measurement
U/L - Laboratory kit

3
Description
Alkaline Phosphatase

Timepoint
before and after intervention

Method of measurement
U/L - laboratory kit

Secondary outcomes

1
Description
TNF-Alpha

Timepoint
Before and after intervention

Method of measurement
Pg/ml - Laboratory kit
<table>
<thead>
<tr>
<th>#</th>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Insulin Resistance</td>
<td>Before and after intervention</td>
<td>based on HOMA-IR</td>
</tr>
<tr>
<td>3</td>
<td>hs-CRP</td>
<td>Before and after intervention</td>
<td>Mg/L - Laboratory kit</td>
</tr>
<tr>
<td>4</td>
<td>Transforming Growth Factor beta (TGF-b)</td>
<td>Before and after intervention</td>
<td>Pg/ml - Laboratory kit</td>
</tr>
<tr>
<td>5</td>
<td>Cytokeratin-18</td>
<td>Before and after intervention</td>
<td>U/L - Laboratory kit</td>
</tr>
<tr>
<td>6</td>
<td>Adiponectin</td>
<td>Before and after intervention</td>
<td>microgram/ml - laboratory kit</td>
</tr>
<tr>
<td>7</td>
<td>Malondialdehyde</td>
<td>Before and after intervention</td>
<td>uM/L - Laboratory kit</td>
</tr>
<tr>
<td>8</td>
<td>Total antioxidant capacity</td>
<td>Before and after intervention</td>
<td>mM Trolox equivalent - laboratory kit</td>
</tr>
<tr>
<td>9</td>
<td>total cholesterol</td>
<td>Before and after intervention</td>
<td>mg/dl - laboratory kit</td>
</tr>
<tr>
<td>10</td>
<td>Triglyceride</td>
<td>Before and after intervention</td>
<td>mg/dl - laboratory kit</td>
</tr>
<tr>
<td>11</td>
<td>LDL-c</td>
<td>Before and after intervention</td>
<td>mg/dl - laboratory kit</td>
</tr>
<tr>
<td>12</td>
<td>HDL-c</td>
<td>Before and after intervention</td>
<td>mg/dl - laboratory kit</td>
</tr>
<tr>
<td>13</td>
<td>Serum Vitamin D</td>
<td>Before and after intervention</td>
<td>ng/ml - Laboratory Kit</td>
</tr>
</tbody>
</table>

**Intervention groups**

1. **Description**
   - Intervention: One pearl of Vitamin D (50000 IU) every other week for 4 months.
   - Category: Treatment - Drugs

2. **Description**
   - Control: Placebo with similarity in physical properties to Vitamin D pearl contains edible paraffin will be prescribed one every other week for 4 months
   - Category: Other
Recruitment centers

1

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Sponsors / Funding sources

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Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jundishapur University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
empty
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan
Deidentified Individual Participant Data Set (IPD)