An assessment of effects of melatonin on metabolic effects of olanzapine in patients with schizophrenia

Protocol summary

Summary

The purpose of this study is to assess the efficacy of melatonin in prevention of olanzapine-induced metabolic side effect in patients with schizophrenia. Forty patients with schizophrenia based on DSM-IV-TR criteria who are not pregnant or lactating and have no significant medical illness will be randomly assigned to treatment for 12 weeks with olanzapine, 15- 25 mg/day, plus melatonin, 3mgs(N=20), or olanzapine, 15-25 mg/day, plus placebo (N=20). This investigation will be conducted in a double-blind fashion. Planned assessments included blood pressure, body weight, body mass index,waist circumference, waist-to-hip ratio, fasting glucose and insulin, insulin resistance index at baseline,week 4,8 &12, and fasting lipids.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201107187049N1**
Registration date: **2011-09-10, 1390/06/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2011-09-10, 1390/06/19

Registrant information
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Recruitment status
  Recruitment complete
Funding source
  Guilan University of Medical sciences

Expected recruitment start date
  2011-08-06, 1390/05/15
Expected recruitment end date
  2012-05-04, 1391/02/15
Actual recruitment start date
  empty
Actual recruitment end date
  empty
Trial completion date
  empty

Scientific title
  An assessment of effects of melatonin on metabolic effects of olanzapine in patients with schizophrenia

Public title
  An assessment of effects of melatonin on metabolic effects of olanzapine in patients with schizophrenia
Purpose
  Prevention
Inclusion/Exclusion criteria
  Inclusion Criteria: age 18-65 year:diagnosis of schizophrenia based on DSM-IV-TR: capability to take drugs at 9.00 pm Exclusion criteria: married women who are at reproductive age; history of drug abuse or dependence in the recent 30 days;history of taking olanzapine in the recent 3 months;history of allergy or intolerance to olanzapine; history of significant head trauma (causing loss of concioussness more than 5 minutes or neurolgical or cognitive sequels);liver, kidney, cerebrovascular or cardiovascular disease;diabetes;metabolic syndrome; cancer ;using antiepileptic , antihypertensive or anticoagulant or anti-platelet drugs; using inhibitors or stimulants of hepatic

isoenzymes that metabolize melatonin or olanzapine (e.g. omeprazole. rifampin, fluvuxamine, ciprofloxacin, carbamazepine, and modafinil) ; patients develop diabetes; acidosis; severe anticholinergic side effects; delirium or need for administration of another drug

Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
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
    Guilan University of Medical sciences
  Street address
    Namjoo street,Rasht
  City
    Rasht
  Postal code
    41446-65385
Approval date
  2011-07-05, 1390/04/14
Ethics committee reference number
  190015211

Health conditions studied

1

Description of health condition studied
  schizophrenia
ICD-10 code
  F20-f29
ICD-10 code description
  Schizophrenia, schizotypal and delusional disorders

Primary outcomes

1

Description
  TRIGLYCERIDE
Timepoint
  baseline,week 4,8,12
Method of measurement
  Enzymatic procedure

2

Description
  waist cicumference
Timepoint
  baseline,week 4,8,12
Method of measurement
  with a plastic meter

3

Description
  body mass index
Timepoint
  baseline,week 4,8,12
Method of measurement
  calculated as body weight(kg)divided by the height in meters square

4

Description
  waist to hip ratio
Timepoint
  baseline,week 4,8,12
Method of measurement
  with a plastic meter

5

Description
  LDL
Timepoint
  baseline,week 4,8,12
Method of measurement
  Enzymatic procedure

6

Description
  HDL
Timepoint
  baseline,week 4,8,12
Method of measurement
  Enzymatic Procedure

7

Description
  FBS
Timepoint
  baseline,week 4,8,12

Method of measurement
   Enzymatic Procedure

8

Description
   Insulin resistance index
Timepoint
   baseline and at the end of intervention
Method of measurement
   with HOMA formula

9

Description
   Fasting serum Insulin values
Timepoint
   baseline and at the end of intervention
Method of measurement
   ELISA

10

Description
   Blood pressure
Timepoint
   baseline,week 4,8,12
Method of measurement
   mercury sphygmomanometer

Secondary outcomes

1

Description
   improvement of sleep problems
Timepoint
   base,week 4,8,12
Method of measurement
   pittsburgh quality of sleep

2

Description
   severity of psychosis
Timepoint
   baseline,week 4,8,12
Method of measurement
   scale measurement by PANSS

Intervention groups

1

Description
   tablet melatonin 3mg at 9 pm as intervention group
Category
   Placebo

2

Description
   placebo at 9 pm as contol group

Category
   Placebo

Recruitment centers

1

Recruitment center
   Name of recruitment center
      Shafa hospital. Guilan University of Medical Sciences
   Full name of responsible person
      Amirhossein Modabbernia
   Street address
      Shafa hospital, Toshiba square, Rasht
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Sponsors / Funding sources

1

Sponsor
   Name of organization / entity
      Guilan University of Medical ScienceS
   Full name of responsible person
      Dr Abdolrasul Sobhani
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   City
      Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
   Yes
Title of funding source
   Guilan 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
Type of organization providing the funding
   empty

Person responsible for general inquiries

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Person responsible for updating data

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Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty