Effect of Iodine treatment in patiënts with COVID-19 disease.

Published: 24-06-2020
Last updated: 19-03-2025

Demonstrate that iodine treatment has a beneficial effect on the course of COVID-19 disease. Beneficial effect is defined as less critically relevant deterioration such as transfers from regular to intensive care units, fewer days of hospitalization...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON49526

Source
ToetsingOnline

Brief title
Iodine treatment Coronavirus infection

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
lunginfection caused by viral infection, Viral infection pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: financiering wordt aangevraagd bij Wetenschapsfonds Maxima MC

Intervention

Keyword: Coronavirus, COVID-19, iodine, treatment

Outcome measures

Primary outcome

Clinically relevant deterioration defined as:

1. transfer from regular ward to IC department

2. death in regular ward depatment

3. death in IC department

Secondary outcome

Total number of days in hospital and total number of deaths.

Study description

Background summary

Iodine has a germicidal effect and contributes to the defense mechanism against pathogens. In addition, Iodine has anti-inflammatory, immune modulating properties and is a very potent scavenger of free oxygen radicals. These properties may have a beneficial effect on the treatment of COVID-19 infections. Several case reports describe a beneficial effect of iodine treatment in viral infections.

Epidemiological research into the number of deceased COVID-19 patients found a striking difference between Japan and Italy. On April 1, 2020, Japan will have 57 deaths with 126 million inhabitants (0.5 / million) and Italy 12,428 deaths with 60 million inhabitants (207 / million). Furthermore, the Japanese are known for their high iodine intake through food, in contrast to Italians who are iodine deficient. The iodine status, measured in Urine Iodine Concentration (UIC) according to the WHO criteria, is 282 mcg / L in Japan and 84 mcg / L in Italy.

The immuno-physiological properties of iodine, the case reports and the epidemiological data suggest a protective effect of iodine against COVID-19 infections. This leads to our hypothesis that iodine is effective in treating COVID-19 infections. To test the hypothesis, we want to investigate the

treatment of iodine in COVID-19 infected patients.

All patients over 18 years of age who are enrolled in Maxima MC are asked to participate in the study.

Exclusion criteria: history of treatment with radioactive iodine, goiter, use of thyroid medication or amiodarone and incapacitation.

The following patient characteristics are collected: age, gender, height, weight, comorbidity, smoking and medication use.

Patients are randomized with the intervention and control group equally divided. Patients in the intervention group receive 3 dd 6 mg (1,5 mg/ml Potassium Jodide) iodine solution for 5 days.
The control group is not given a placebo supplement.

Outcome measures are:
Primary: clinically relevant deterioration defined as transfer from regular nursing unit to intensive care unit or death.
Secondary: total number of days in hospital and total number of deaths.

In addition, the cumulative amount of iodine used per patient is registered and other medication used in the context of the COVID-19 infection.

Study objective

Demonstrate that iodine treatment has a beneficial effect on the course of COVID-19 disease. Beneficial effect is defined as less critically relevant deterioration such as transfers from regular to intensive care units, fewer days of hospitalization and less death.

Study design

Open label randomized trial with a control group.

Intervention

Patients in the intervention group receive 1 dd 1/4 PotassiumJodide 65 mg tablet for 8 days.
The control group is not given a placebo supplement.

Study burden and risks

the inconvenience of taking 1 dd 1/4 PotassiumJodide 65 mg tablet for 8 days is negligible.

Risk of side effects are minimale en temporary.

Contacts

Public
Maxima Medisch Centrum

De Run 4600
Veldhoven 5504 DB
NL
Scientific
Maxima Medisch Centrum

De Run 4600
Veldhoven 5504 DB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Hospitalization and positive test for SARS-CoV-2 infection

Exclusion criteria

Thyroid disease or treatment like goiter, thyroidectomie, radioactive iodine, medication related to thyroid dysfunction or the use of Amiodaron

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-10-2020
Enrollment:	224
Type:	Actual

Ethics review

Approved WMO Date:	24-06-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	14-07-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25013
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2020-001852-16-NL
CCMO	NL73784.028.20
OMON	NL-OMON25013
OMON	NL-OMON26738