Evaluation of the Daily Intake of 0.5 L of Water Saturated With Molecular Hydrogen for 21 Days in COVID-19 Patients Treated in Ambulatory Care (HYDRO COVID)

ClinicalTrials.gov Identifier: NCT04716985

Recruitment Status : Recruiting
First Posted : January 20, 2021
Last Update Posted : October 25, 2021

See Contacts and Locations

Sponsor:
AGIR à Dom

Collaborators:
Laboratoire TIMC-IMAG
DrinkHRW, British Columbia, Canada

Information provided by (Responsible Party):
AGIR à Dom

Study Description

Brief Summary:

Through its anti-inflammatory role, molecular hydrogen could have a beneficial effect in preventing the runaway inflammatory reactions that lead to complications of Covid-19.

This hypothesis is supported by numerous preclinical and theoretical arguments, as well as by some Chinese clinical studies (the Chinese guidelines for the management of Covid-19 recommend the inhalation of hydrogen), a recommendation whose interest has just been confirmed by a publication describing the very positive results of a clinical study in China.

Through its anti-inflammatory role, molecular hydrogen could have a beneficial effect in preventing the runaway inflammatory reactions that lead to complications of Covid-19.

The ingestion of water saturated with molecular hydrogen has been the subject of several clinical studies in other indications than Covid-19, and no side effects of this ingestion have been reported. A recent publication recommends initiating clinical trials using a hydrogen fortified beverage.

Condition or disease	Intervention/treatment	Phase
SARS-CoV-2 Covid19 AMBULATORY CARE	Dietary Supplement: MOLECULAR HYDROGEN Dietary Supplement: PLACEBO MAGNESIUM	Not Applicable

▸ Show detailed description

Study Design

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	580 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	Double-blind, randomized, multicentre comparative study.
Masking:	Triple (Participant, Investigator, Outcomes Assessor)
Masking Description:	They will be labeled study (randomization number to respect blind and legal notices labeling clinical research).
Primary Purpose:	Prevention
Official Title:	Evaluation of the Daily Intake of 0.5 L of Water Saturated With Molecular Hydrogen for 21 Days in COVID-19 Patients Treated in Ambulatory Care. Double-blind, Randomized, Comparative Study
Actual Study Start Date :	January 22, 2021
Estimated Primary Completion Date :	May 22, 2022
Estimated Study Completion Date :	May 22, 2023

Resource links provided by the National Library of Medicine

MedlinePlus related topics: COVID-19 (Coronavirus Disease 2019) Drinking Water

Drug Information available for: Magnesium

U.S. FDA Resources

Arms and Interventions

Arm	Intervention/treatment
Active Comparator: TREATMENT GROUP Water saturated with molecular hydrogen at the rate of 2 times 250 mL / day for 21 days. 80 mg of Mg metal, and safe excipients (dextrose, malic acid, L-tartaric acid, adipic acid).	Dietary Supplement: MOLECULAR HYDROGEN Magnesium Tablet
Placebo Comparator: PLACEBO GROUP Water saturated with magnesium at the rate of 2 times 250 mL / day for 21 days. 80 mg of Mg, but in ionic form.	Dietary Supplement: PLACEBO MAGNESIUM Magnesium carbonate tablet

Outcome Measures

Primary Outcome Measures :

1. Change in the incidence rate of the onset of clinical worsening [Time Frame: 12 to 14 days]

   Demonstrate that the daily ingestion of 250 mL twice a day, i.e. 0.5 L of water saturated with molecular hydrogen for 21 days compared to water not enriched in hydrogen, decreases the incidence rate of the appearance of clinical worsening in patients within 12 to 14 days following a COVID-19 + diagnosis with outpatient care.

   The primary endpoint is a composite endpoint combining worsening of dyspnea, fatigue, putting on 02, hospitalizations, death occurring within 12 to 14 days of inclusion in the study.

   The worsening of dyspnea, fatigue being defined as an increase of 25% via Chalder scale for fatigue, MMRC scale for dyspnea.

   Chalder scale with 11 items (mental 7 questions yes/no and physical symptoms 4 questions yes/no) MMRC scale with 4 stades (stade 0 "no dyspnea" to 4 "strong dyspnea")

Secondary Outcome Measures :

1. Assessment of tolerance [Time Frame: 30 days]

   Evaluate the tolerance to the treatment during the first 30 days (via a logbook of symptomatic events).

2. Assessment of compliance [Time Frame: 21 days]

   Evaluate compliance with treatment by the frequency, percentage of expected intake using a logbook filled in by the patient during the 21 days of taking the treatment (at least 80% using a logbook collecting symptomatic events). Frequency and percentage will be combined to report observance.

3. Assessment of medium-long term dyspnea symptoms [Time Frame: 30 Days, 3 months, 12 months]

   Evaluate in the symptoms at 30 Days, 3 months, 12 months for dyspnea via the modified MMRC Borg scale. The MMRC Borg scale contains 5 questions, stade 0 for dyspnea with strong effort and stade 4 for dyspnea with light effort.

4. Assessment of medium-long term fatigue symptoms [Time Frame: 30 Days, 3 months, 12 months]

   Evaluate in the symptoms at 30 Days, 3 months, 12 months for fatigue via the Chalder scale. The Chalder scale contains 2 domains (physical and mental symptoms), with a total of 11 questions yes/no, answer yes correspond to the presence of symptom.

5. Assessment of oximetry symptoms [Time Frame: 30 Days]

   Evaluate in the symptoms at 30 Days for pulse oximetry during the first 30 days. Pulse oximetry will be reported daily by the patient on the logbook (one measure/day).

6. Assessment of quality of life [Time Frame: 30 days, 3 months, 12 months]

   Evaluate the quality of life via EQ5D5L scale. EQ-5D-5L is a standardized instrument developed by the EuroQol Group as a measure of health-related quality of lige that can be used in a wide range of health conditions and treatments. The EQ5D has 6 items intended to measure general health. The top 5 rate mobility, independence, daily activities, pain / discomfort, and anxiety / depression, and are rated according to 5 values : "No problem", "little problem", "moderate problem", "high problem" and "Incapacity". This results in an index score. The last item deals with perceived health on the day the questionnaire is filled in and uses a visual analogue scale from 0 (wors) to 100 (best health possible) (Visual Analog Scale Score)

7. Assesment of sleep quality [Time Frame: 30 days, 3 months, 12 months]

   Evaluate the quality of sleep by PSQI scale (11 questions). The PSQI scale (Pittsburgh Sommeil Qualité Index) contains 19 questions (auto evaluation) and 5 questions for nearby. A total score of 21 points will be obtained (0 for no difficulties, 21 for major difficulties).

8. Assessment of care consumption [Time Frame: 30 days, 3 months, 12 months]

   Evaluate the consumption of care via the patient notebook (hospitalizations, medical consultations).

9. Assessment of blind treatment [Time Frame: 30 days]

   Evaluate the blind by CRA survey (question by phone on the potential drug group)

10. Assessment of COVID-19 contact cases [Time Frame: 30 days]

    Evaluate the number of COVID-19 among contact cases per CRA survey

11. Assessment of risk factors [Time Frame: 30 days, 3 months, 12 months]

    Evaluate the risk factors (age, comorbidities), physical activity, nutritional status (weight) before and after COVID-19 infection via the patient notebook. Comorbidities, physical activity, nutritional status will be combined to report risk factors.

12. Analysis of older patients [Time Frame: inclusion]

    Sub group analysis on the primary outcome measure (stratification on age at inclusion > or = 70 years).

13. Assessment of pain [Time Frame: 14 days, 30 days, 3 months, 12 months]

    Evaluate the pain via regular EVA score, DN4 (Douleur Neuropathique 4) Questionnaire (10 questions/4 domains) a total score will be obtain (0 no neuropathic pain, 10 major neuropathic pain).

Eligibility Criteria

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

Criteria

Inclusion Criteria:

- Age 18 to 59 years old or over 60 years old.
- If patient 18 to 59 years old, presence of at least one risk factor :
  - Hypertension under treatment (all stages)
  - Obesity (BMI ≥30 kg / m2)
  - Diabetes under treatment (all types)
  - Stable ischemic heart disease (all stages)
  - Atrial fibrillation
  - Stable heart failure (all stages)
  - History of stroke
  - Stage 3 chronic renal failure (30 ≤ estimated GFR <60 mL / min / 1.73 m²)
  - COPD (all stages, including chronic respiratory failure under long-term oxygen therapy)
  - Solid tumors or malignant hemopathies that are progressive or whose diagnosis is less than 5 years old
  - Immunodeficiency:
- of therapeutic origin (solid organ transplantation or transplant of hematopoietic stem cells, anticancer chemotherapy, immunosuppressive treatment, corticosteroid therapy> 15 mg / day equivalent to prednisone price for at least 2 months);
- or HIV infection and last known CD4 count <200 / mm3
  - History of pulmonary embolism and / or proximal deep vein thrombosis
  - Asthma under inhaled corticosteroid therapy
  - Paired sleep apnea syndrome
  - Peripheral arterial disease of the lower limbs stage II and above
  - Another risk factor presented, according to the list defined by the French High Council of Public Health
  - OR Presence of at least 3 comorbidities, according to the Rapid Responses to COVID-19 from the French High Council of Public Health.
- Patient with nasopharyngeal swab (antigenic test, RT-PCR, or other HAS-validated swabs to come) :
  - In case of positive test (antigenic test, RT-PCR, Other), patient with at least 1 symptom at the time of testing:
  - In case of negative antigenic or other test or ongoing or uninterpretable RT-PCR test, the patient must present at least 3 of the 11 symptoms of COVID-19 dating back no more than 4 days as defined below and notion of contact (with a certain or probable COVID+ patient) dating back less than 10 days:

Fever > 37,5°C since 3 days Cough Sore throat/cold Headache Anosmia, dysgeusia Myalgias, arthralgias, bone pain Respiratory difficulties (feeling of dyspnea at rest) Chest pain (sternal) Digestive complaints (diarrhea, nausea, vomiting) Tachycardia (palpitation) Conjunctivitis (red eyes)

- No seriousness signs during the consultation and for at least 72 hours.
- Patient able to understand the procedure and follow it and have tools for a video-consultation.
- Affiliation to the social security system.
- Voluntary to participate to the study, informed consent form signed after appropriate information

Exclusion Criteria:

- The absence of attending or referring physician
- Any sign of seriousness incompatible with home care.
- Severe chronic kidney failure or dialysis (i.e. DFGe <30).
- drink cure Contraindication (500 ml/d for 21 days).
- Contraindication to any drug in the study, including a known allergy, especially magnesium.
- Uncontrolled and clinically significant heart disease, whether its origin (arrhythmias, angina, uncompensated congestive heart failure).
- Subject participating to an other clinical study interventional.
- Person deprived of liberty or under legal guardianship.
- No one in the same household who participated in this study.
- Patient refusing hospitalization.
- Persons subject to sections L1121-7 and L1121-8 of the CSP (minor, person deprived of liberty by judicial or administrative decision, person subject to a legal protection measure) or not able to communicate his consent verbally.

Contacts and Locations

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): ***NCT04716985***

Contacts

Contact: Jean-luc BOSSON, Professor   0033476765040   jean-luc.bosson@univ-grenoble-alpes.fr
Contact: Carole CR ROLLAND   0033476765040   carole.rolland@univ-grenoble-alpes.fr

Locations

France

Timc-Imag (Umr5525 Uga-Cnrs) — **Recruiting**
Grenoble, France, 38000
Contact: Yoann Gaboreau, DR

Morocco

Casablanca center — **Not yet recruiting**
Casablanca, Morocco
Contact: JAFAAR HEIKEL

Serbia

Public Health Center — **Not yet recruiting**
Sremska Kamenica, Serbia
Contact: Aleksandra Milovancev
Principal Investigator: Aleksandra Milovancev, MD
Sub-Investigator: Jovana Avakumovic, MD
Sub-Investigator: Milijana Čelarević, MD
Sub-Investigator: Danijela Musulin Banjanin, MD

Sponsors and Collaborators

AGIR à Dom
Laboratoire TIMC-IMAG
DrinkHRW, British Columbia, Canada

Investigators

Principal Investigator: Yoann Gaboreau, Dr   Laboratoire TIMC Equipe Themas

More Information

Additional Information:

High Council of Public Health. Opinion of 29 October 2020 on the updating of the list of risk factors for the severe form of COVID-19

High Authority of Health. Rapid responses in the context of Covid-19 - Primary care of patients suspected of Covid-19. Paris, June 18, 2020. Updated in Nov 2020

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TY - JOUR AU - Russell, Grace AU - Veal, David AU - Rehman, Mubasher AU - Adukwu, Emmanuel AU - LeBaron, Tyler AU - Hancock, John PY - 2020/06/22 SP - T1 - An Overview of SARS-CoV-2 (COVID-19) Infection and the Importance of Molecular Hydrogen as an Adjunctive Therapy DO - 10.20455/ros.2020.829 JO - Reactive Oxygen Species ER -

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Responsible Party:	AGIR à Dom
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Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Keywords provided by AGIR à Dom:
MOLECULAR HYDROGEN
anti-inflammatory role

Additional relevant MeSH terms:

COVID-19	Coronavirus Infections
Respiratory Tract Infections	Coronaviridae Infections
Infections	Nidovirales Infections
Pneumonia, Viral	RNA Virus Infections
Pneumonia	Lung Diseases
Virus Diseases	Respiratory Tract Diseases