To Develop Methods for the Rehabilitation of Chronic Gastroduodenal Pathology in Children.

STUDY DESCRIPTION

Brief Summary

The object of the study will be children and adolescents from 6 to 15 years old, living in the city of Tashkent and in the Tashkent region. We will study patients with various clinical forms of chronic gastroduodenal pathology (CGDP). The effect of enteral oxygen therapy in the recovery of patients with CGDP due to the positive effect of the active form of oxygen on the hematological system and on the regenerative processes in the gastrointestinal tract will be studied. At the same time, the effect of enteral oxygen therapy on enhancing the effectiveness of eradication therapy during the treatment of carrier Helicobacter pylori due to the neutralization of the products of urea hydrolysis around bacteria under the action of reactive oxygen species will be studied.

Condition or Disease: Gastritis Chronic, Gastroduodenitis, Peptic Ulcer, Duodenal Ulcer

Intervention/treatment: Drug: Enteral oxygen therapy

Phase: Not Applicable

DETAILED DESCRIPTION

In recent years, among the non-infectious diseases of children and adolescents, there has been an increase in many nosological forms of pathology of the gastrointestinal tract. Scientific works of recent years show that all over the world much attention is paid to the problem of timely prevention and improvement of chronic diseases of the gastroduodenal zone in children. This is mainly due to the fact that the incidence of diseases of the digestive system among schoolchildren is steadily increasing. In the clinical practice of gastroenterologists, it is often necessary to influence the regeneration processes in the gastroduodenal zone. The object of the study will be children and adolescents from 6 to 15 years old, living in the city of Tashkent and in the Tashkent region. We will study patients with various clinical forms of chronic gastroduodenal pathology (CGDP). The effect of enteral oxygen therapy in the recovery of patients with CGDP due to the positive effect of the active form of oxygen on the hematological system and on the regenerative processes in the gastrointestinal tract will be studied. At the same time, the effect of enteral oxygen therapy on enhancing the effectiveness of eradication therapy during the treatment of carrier Helicobacter pylori due to the neutralization of the products of urea hydrolysis around bacteria under the action of reactive oxygen species will be studied.

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment: 320 participants

Intervention Model Description: Comparison of 2 mutually comparable patient groups.

Intervention Model: Single Group Assignment

Masking: None (Open Label)

Primary Purpose: Supportive Care

Official Title: To Develop Methods for the Rehabilitation of Chronic Gastroduodenal Pathology in Children.

ARMS AND INTERVENTIONS

Arm | Intervention/treatment
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Experimental: Enteral oxygen therapy for the improvement of children with chronic gastroduodenal pathology. Enteral oxygen therapy is prescribed for children with chronic gastroduodenal pathology during the recovery period, after inpatient treatment, for 14 days, every day, in the form of an oxygen cocktail. An oxygen cocktail is prepared on the basis of a pharmaceutical product using herbal ingredients. The patient takes a 200 ml oxygen cocktail, using a small spoon, during the daytime.

Drug: Enteral oxygen therapy

Intervention during the rehabilitation period of patients with CGDP.

OUTCOME MEASURES

Primary Outcome Measures: 1. Initial clinical examination of children and adolescents at risk of CGDP. [Time Frame: 2 weeks]

A clinical examination of patients will be carried out, consisting of: identification of complaints - epigastric pain, dyspeptic symptoms - vomiting, panos, constipation, loss of appetite (oral questioning based on standard questions and scale HBSC (Health Behaviour in School-aged Children, A.King, 1996); collection of data on the presence in the family of a patient with this disease (oral survey based on standard questions); general examination of the patient - the presence of abdominal pain syndrome, stiffness of the abdominal muscles, intestinal distention (palpation, percussion, auscultation).
2. Identification of Helicobacter pylori infection. [Time Frame: 2 weeks]
   The study for Helicobacter pylori (HP) infection will be based on the qualitative determination of the pathogen by two mutually unrelated methods: using a breath test (HELIK® test system with an indicator tube) and an immunochromatographic fecal sample for the presence of occult blood (erythrocyte cells). The interpretation of the test is either "positive" or "negative". The patient will be considered HP infected if both tests are positive.

3. Esophagogastroduodenoscopy at the start of the study [Time Frame: 2 weeks]
   Esophagogastroduodenoscopy is carried out with an assessment of the endoscopic picture of the visible mucous membranes of the stomach and duodenum according to the criteria of the generally accepted Sydney classification (1990, with a modification of 1996), with a description of the visible mucous organ: the presence of areas of hyperemia, ulcers, atrophy, hypertrophy, scarring (visual description).

4. Treatment of identified patients. [Time Frame: 6 weeks]
   If a disease is detected, the patient will be referred for treatment to a specialized children's hospital (Tashkent), where he will receive appropriate treatment according to generally accepted standards. The effectiveness of treatment will be assessed by the manifestation of clinical symptoms: the presence of complaints - epigastric pain, dyspeptic symptoms - vomiting, anorexia, constipation, loss of appetite (oral questioning based on standard questions); general examination of the patient - the presence of abdominal pain syndrome, stiffness of the abdominal muscles, intestinal distention (palpation, percussion, auscultation).

5. Rehabilitation of patients using enteral oxygen therapy. [Time Frame: 6 weeks]
   Rehabilitation of children and adolescents with chronic gastroduodenal pathology after inpatient or outpatient treatment using enteral oxygen therapy is carried out. Studies will be conducted on the content in the peripheral blood in patients: hemoglobin (HGB, Hb, g/dL), erythrocytes (RBC, x 1012/L), the content of hemoglobin in the erythrocyte (MCH, pg/cell), concentration in the erythrocyte of hemoglobin (MCHC, g/dL). EFGDS is performed with an assessment of the endoscopic picture of the visible mucous membranes of the stomach and duodenum, according to the criteria of the generally accepted Sydney classification (1990, with a modification of 1996), with a description of the visible mucous organ: the presence of areas of hyperemia, ulcers, atrophy, hypertrophy, scarring.

6. Esophagogastroduodenoscopy after rehabilitation. [Time Frame: 2 weeks]
   After rehabilitation measures using enteral oxygen therapy, repeated esophagogastroduodenoscopy (EFGDS) will be performed. EFGDS is carried out with an assessment of the endoscopic picture of the visible mucous membranes of the stomach and duodenum according to the criteria of the generally accepted Sydney classification (1990, with a modification of 1996), with a description of the visible mucous organ: the presence of areas of hyperemia, ulcers, atrophy, hypertrophy, scarring (visual description).

Secondary Outcome Measures:
1. Statistical data processing. [Time Frame: 4 weeks]
   Statistical data processing will be carried out using Microsoft Excel 7.0 for Windows-XP, with the definition of the arithmetic mean (M) and standard deviation (s). When characterizing the statistical significance of the differences, the Student's t-test was used, with the determination of the limit of the confidence interval based on the Student's distribution table. The results will be assessed as statistically significant at a probability level of P <0.05. Comparison is made between groups of patients receiving enteral oxygen therapy and those not receiving.

ELIGIBILITY CRITERIA

Ages Eligible for Study: 6 to 15 Years (Child)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:
children and adolescents aged 6 to 15 years; children with chronic gastroduodenal pathology: chronic gastritis, chronic gastroduodenitis, chronic duodenitis, gastric and intestinal ulcers of both sexes; children who have the opportunity to visit the clinic.

Exclusion Criteria:
children under 6 years old and adolescents over 15 years old; children with chronic diseases of internal organs, except for the gastrointestinal tract; children with psychosomatic and neurological disorders; children in hospital; children with endocrine diseases; children who are allergic to eggs; children with blood diseases; children with cancer.

CONTACTS AND LOCATIONS

Contacts

Uzbekistan

Tashkent Pediatric Medical Institute

Tashkent

Sponsors and Collaborators

Tashkent Pediatric Medical Institute

Investigator

Study Director: Shokhida Turdieva, MD Tashkent Pediatric Medical Institute

MORE INFORMATION

Responsible Party: Tashkent Pediatric Medical Institute

ClinicalTrials.gov Identifier: NCT04702542

Other Study ID Numbers: TashkentPediatricMI-2

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Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Plan Description: Joint study of the regenerative properties of oxygen in chronic pathology of the gastrointestinal tract.

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Keywords provided by Tashkent Pediatric Medical Institute:

- children
- duodenal ulcer
- gastritis
- gastroduodenitis
- Helicobacter pylori oxygen therapy
- rehabilitation
- peptic ulcer
- teenagers

Additional relevant MeSH terms:

- Peptic Ulcer
- Gastritis
- Gastroenteritis
- Intestinal Diseases
- Duodenal Ulcer
- Digestive System Diseases
- Stomach Diseases
- Pathologic Processes
- Gastroenteritis
- Duodenal Diseases