Clinical Trial With Clobetasol and Dexamethasone for Topical Treatment of Oral Lesions of Chronic Graft-versus-host Disease

ClinicalTrials.gov Identifier: NCT01699412

Recruitment Status: Completed
First Posted: October 3, 2012
Last Update Posted: October 3, 2012

Sponsor:
Grupo de Estudos Multicentricos em Onco-Hematologia

Information provided by (Responsible Party):
Grupo de Estudos Multicentricos em Onco-Hematologia

Study Description

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Brief Summary:
The purpose of this study is to perform a randomized, double-blind, clinical trial comparing the topical treatment with clobetasol or dexamethasone for symptomatic oral lesions of chronic graft-versus-host disease.

Condition or disease	Intervention/treatment	Phase
Graft vs Host Disease Oral Manifestations	Drug: Clobetasol Drug: Dexamethasone	Phase 3

Detailed Description:

All patients with symptomatic oral lesions of cGVHD were included in the study. Exclusion criteria were patients with 12 years or less of age, history of allergy to any of the studied medications and patients already under other topical treatment for oral lesions of cGVHD. Patients were randomly assigned between two study groups: one group rinsed with a solution of clobetasol propionate 0.05% associated to nystatin 100,000 UI/mL; and another group rinsed with a solution of dexamethasone 0.1 mg/ml associated to nystatin 100,000 UI/mL. Patients were instructed to use the solution 3 times a day, during 1 minute, for 28 days. Clinical exams were performed at baseline and after 28 days. Patients were evaluated by an oral medicine expert, previously calibrated for evaluation of oral cGVHD lesions. Oral lesions of cGVHD were diagnosed according to NIH 2005 criteria, and graded according to the modified oral mucositis rating scale. Evaluation of the symptoms of the oral mucosa and of xerostomia were performed through visual analogue scale. Samples for fungal culture were obtained before and after the topical treatment. Results were submitted to a descriptive analysis. Chi-square was used for the comparison of categorical variables. Mann-Whitney and Wilcoxon tests were used for the comparison of measurable data inter and intra-groups, respectively. Significance level was set at 5%.

Study Design

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Study Type:	Interventional (Clinical Trial)
Actual Enrollment:	28 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	Randomized Double-blid Clinical Trial Comparing the Topical Treatment With Clobetasol and Dexamethasone for Oral Lesions of Chronic Graft-versus-host Disease in Allogeneic Hematopoietic Stem Cell Transplant Recipients
Study Start Date:	August 2008
Actual Primary Completion Date:	July 2012
Actual Study Completion Date:	August 2012

resources: Homologous Wasting Disease

Chronic Graft Versus Host Disease

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Dexamethasone Patients under topical treatment with solution of dexamethasone 0.1 mg/mL associated to nystatin 100,000 UI/mL	Drug: Dexamethasone Rinse with a solution of dexamethasone 0.1 mg/mL associated to nystatin 100,000 UI/mL, for 1 minute, during 28 days
Experimental: Clobetasol Patients under topical treatment with solution of clobetasol 0.05% associated with nystatin 100,000 UI/mL	Drug: Clobetasol Rinse with a solution of clobetasol 0.05% associated to nystatin 100,000 UI/mL, for 1 minute, during 28 days

Outcome Measures

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Primary Outcome Measures:

1. Change from baseline in symptoms related to oral cGVHD at 4 weeks [Time Frame: Baseline and 4 weeks]

   Comparison of symptoms of oral lesions of chronic GVHD, analyzed through visual analogue scale, at baseline and after 4 weeks of topical treatment

Secondary Outcome Measures:

1. Change from baseline in clinical aspects of oral cGVHD at 4 weeks [Time Frame: Baseline and 4 weeks]

   Comparison of the morphologic response of the oral lesions of chronic GVHD, measured through modified Oral Mucositis Rating Scale

Eligibility Criteria

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Information from the National Library of Medicine NIH NLM

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

Criteria

Inclusion Criteria:

- Patients with symptomatic oral lesions of chronic graft-versus-host disease

Exclusion Criteria:

- Patients with less than 12 years of age
- Patients physically of mentally disabled
- History of allergy to any of the medications under study
- Patients already under topical treatment for oral lesions of chronic GVHD

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT01699412***

Locations

Brazil

Hematology and Hemotherapy Center
Campinas, São Paulo, Brazil, 13083-878

Clementino Fraga Filho University Hospital
Rio de Janeiro, Brazil, 21941-913

Sponsors and Collaborators

Grupo de Estudos Multicentricos em Onco-Hematologia

Investigators

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More Information

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Publications:

Noce CW, Gomes A, Copello A, Barbosa RD, Sant'anna S, Moreira MC, Correa ME, Maiolino A, Torres SR. Oral involvement of chronic graft-versus-host disease in hematopoietic stem cell transplant recipients. Gen Dent. 2011 Nov-Dec;59(6):458-62; quiz 463-4.

Responsible Party:	Grupo de Estudos Multicentricos em Onco-Hematologia
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Keywords provided by Grupo de Estudos Multicentricos em Onco-Hematologia:
Bone Marrow Transplantation
Graft vs Host Disease
Oral Manifestations

Additional relevant MeSH terms:

Graft vs Host Disease	Peripheral Nervous System Agents
Oral Manifestations	Physiological Effects of Drugs
Immune System Diseases	Gastrointestinal Agents
Mouth Diseases	Glucocorticoids

Stomatognathic Diseases
Signs and Symptoms
Pharmaceutical Solutions
Dexamethasone acetate
Dexamethasone
Clobetasol
BB 1101
Nystatin
Anti-Inflammatory Agents
Antiemetics
Autonomic Agents
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Antineoplastic Agents, Hormonal
Antineoplastic Agents
Protease Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Anti-Bacterial Agents
Anti-Infective Agents
Antifungal Agents
Ionophores