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Development and evaluation of polymeric in situ gels of antifungal agents for oral candidiasis

Submission date	Recruitment status	[_] Prospectively registered
01/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/09/2011	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Development and evaluation of polymeric in situ gels of antifungal agents for oral candidiasis: A single blind, randomised controlled trial

Study objectives
1. To assess the effect of fluconazole in situ gels locally applied in the oral cavity on the number of Candida species
2. To assess the therapeutic efficacy of the dosage for in eradiation of local candidiasis
3. To estimate the drug release with respect to time in the oral cavity
4. To understand whether the present dosage will help to improve patient compliance using Likert's rating scale

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee at A.B.Shetty Memorial Institute of Dental Sciences approved on the 25th of June 2008 (ref: ABSM/EC/18/2008)

Study design
2 centre single blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Oropharyngeal candidiasis

Interventions
A bicenter, open-label, single blind clinical trial design was followed, to compare the efficacy of fluconazole in situ gel (0.5% w/v) with that of fluconazole tablets (100 mg) for 14 days. The patients with OPC were divided into 3 groups, each comprising of 15 patients.
1. Group I: comprised of patients having HIV/AIDS treated with in situ gel
2. Group II: comprised of patients with partial or complete dentures, treated with in situ gel
3. Group III (active control): comprised of patients with either HIV or partial/complete dentures were treated with fluconazole tablets 100 mg for 14 days given by oral route

Following the initial (base line) visit, the subsequent visits were scheduled on day 3, day 7, day 14, day 22, day 34, and 44th day. The efficacy of the dosage form was compared with tablets for the successful clinical response and changes from baseline for the symptoms of OPC, which included the soreness erythema, extent of oral lesions and quantification of colony forming units (CFU) of Candida spp. Clinical assessment were made and recorded by a Registered clinical practitioners. The severity of baseline symptoms was assessed on a scale of 0 to 3 (0= absent, 1= mild, 2= moderate, 3= severe).
The quantification of CFU of Candida spp., was done by taking oral swabs at three different locations. Oral swabs were then streaked on hichrome® medium. The specimen was examined microscopically for hyphae, colour of colony to distinguish the strain. The microscopic study of the culture was done before the drug was dispensed.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Fluconazole

Primary outcome(s)
The primary efficacy parameter for clinical response was rated according to an evaluations assessment of the change in signs and symptoms from the baseline. The assessment was rated as "cured" (clearance of all signs and symptoms), "improved" (minimal signs and symptoms with no residual visible candida lesions), unchanged (no change in signs and symptoms), or "deteriorated" (worsening or increasing signs and symptoms). Patients with a clinical evaluation of "cured" or "improved" were considered as a successful outcome of the study.

Key secondary outcome(s))
Secondary efficacy parameters included the quantification in terms of CFUs of Candida spp. and results of culture from swabs taken at the same sites used at baseline. A mycological cure was defined as a yeast quantification of <10 CFU/ml based on comparison of mycological culture from swabs collected from healthy volunteers.
To analyze the data of clinical efficacy statistically, a two-factor repeated measures analysis of variance was used between the treated groups over a period of 44 days. The criterion for significance was set at $p<0.05$.

Completion date
05/09/2008

Eligibility

Key inclusion criteria
1. Patients of either sex, aged 18 or above
2. HIV-antibody seropositive or with partial or complete denture and the clinical picture of oropharyngeal candidiasis (OPC), which is characterised by creamy, white, curd like patches, removable erythematous lesions on the oral mucosal surfaces

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
1. History of significant hepatic abnormalities or clinical evidence of significant hepatic diseases within 2 months of entering the study
2. Life expectancy of less than 1 month or a clinical condition such that study completion could not be assured
3. History of hypersensitivity to imidazole or azole compound
4. Patients requiring therapy with other antifungal agents, H2-receptor blockers, antacids, rifampicin, phenobarbital,
pheytoin, carbamazeme, terfenadine, or astimazole
5. Pregnant or lactating females

Date of first enrolment
20/07/2008

Date of final enrolment
05/09/2008

Locations

Countries of recruitment
India

Study participating centre
Department of Pharmaceutics
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Sponsor information

Organisation
Nitte University (India)

ROR
https://ror.org/029nydt37

Funder(s)

Funder type
University/education

Funder Name
Rajiv Gandhi University of Health Sciences (India)

Alternative Name(s)
Rajiv Gandhi University of Health Sciences, Karnataka, RGUHS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
India

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/04/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes