PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

A Phase II, Multi-center, Randomised, Double-blind, Placebo-controlled Study Comparing the Efficacy and Safety of Clonidine Lauriad™ 50 µg and 100 µg Mucoadhesive Buccal Tablet (MBT) Applied Once Daily to Those of Placebo in the Prevention and Treatment of Chemoradiation Therapy Induced Oral Mucositis in Patients With Head and Neck Cancer

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**The purpose of this study is to evaluate the efficacy and safety of Clonidine Lauriad™ to
treat chemoradiation therapy induced severe oral mucositis in patients with head and neck
cancer.**

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00003459**
- Date of Registration in DRKS: **2012/05/05**
- Date of Registration in Partner Registry or other Primary Registry: **2011/06/29**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT01385748 (ClinicalTrials.gov)**
- Sponsor-ID: **BA2009/28/01 (BioAlliance Pharma SA)**

Health condition or Problem studied

- Free text: **Oral Mucositis**
- ICD10: **K12.3 - Oral mucositis (ulcerative)**

Interventions/Observational Groups

- Arm 1: **Drug: Clonidine Lauriad 50µg**
- Arm 2: **Drug: Clonidine Lauriad 100µg**
- Arm 3: **Drug: Placebo Lauriad**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, caregiver, investigator/therapist**
- Control: **Placebo, Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Percentage of patients with an oral mucositis score≥ 3 using the WHO scale at cumulative radiation dose of 50 Gy; time frame: 8 weeks; Comparison between groups of the percentage of patients with an oral mucositis score ≥ 3 using the WHO scale at cumulative radiation dose of 50 Gy.

Secondary Outcome

- Percentage of patients with an oral mucositis score≥ 3 using the WHO scale at cumulative radiation doses of 40 Gy and 60 Gy; time frame: 8 weeks

Countries of recruitment

- US **United States**
- FR **France**
- DE **Germany**
- HU **Hungary**
- ES **Spain**
- CH **Switzerland**

Locations of Recruitment

- **Universitatsklinikum Essen, Essen**
- **Universitatsklinikum Freiburg Klinik fur Strahlentherapie, Freiburg**
- **Universitatsklinikum Leipzig, Leipzig**
- **Paracelsius- Klinik, Osnabruck**
- **Universitatsklinikum Regensburg Klinik und Poliklinik fur, Regensburg**
- **Arztehaus an der Ammerlandklinik, Westerstede**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/04/30**
- Target Sample Size: **183**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Male or female

- Aged > 18 years

- Suffering from a newly diagnosed squamous cell carcinoma of the oral

cavity,
oropharynx, hypopharynx or larynx histologically-confirmed and having undergone
resective surgery

- Prior neoadjuvant chemotherapy allowed provided that, the patient did not experience
a WHO grade > 2 oral mucositis during the neoadjuvant therapy.

- Patient eligible to receive concurrent chemo-radiation defined as:

1. A continuous course of conventional external beam irradiation (IMRT eligible)
with a minimum cumulative radiation dose of 50 Gy or a maximum of 70 Gy, based
on a daily dosing between 1.8 and 2.2 Gy combined with platinum based
chemotherapy on a weekly or tri-weekly cycles.

2. Planned radiation treatment fields must include at least two oral tissue sites
(among right or left buccal mucosa, floor of mouth, tongue, right or left soft
palate) with each site receiving a total of 50 Gy or a maximum of 70 Gy. The
radiation treatment plan will be reviewed by a designated radiation oncologist.

- ECOG performance status ≤2

- Screening laboratory tests:

1. Haemoglobin ≥ 10g/dL

2. Absolute neutrophil counts ≥ 1500 cells/mm3

3. Platelets ≥ 100.000/mm3

4. Conjugated bilirubin ≤ 2 times Upper Limit of Normal (ULN)

5. Serum AST and ALT ≤ 3 ULN

6. Negative serum pregnancy test

- Women of child bearing potential must have effective contraception method (oral or
device)

- Signed written informed consent

Exclusion criteria

- Tumours of the lips, sinuses, salivary glands

- Prior radiation of the head and neck area

- Curative surgery less than 2 weeks or more than 15 weeks prior to the initiation of RT-CT

- Presence of active infectious disease

- Presence of active oral infectious disease, including oropharyngeal candidiasis and/or orofacial herpes

- Presence of oral mucositis

- Known or suspected chronic viral diseases including HIV

- Systolic blood pressure < 100 mmHg and/or Diastolic blood pressure < 50 mmHg

- Recent stroke within the last 6 months

- Bradyarrhythmia (<60 b/min), including sinus node dysfunction or AV nodal conduction block 2nd or 3rd degree

- Subjects with orthostatic hypotension, defined by a decrease of systolic BP and/or diastolic BP above 20 mmHg when the patient stands up

- Renal insufficiency (creatinine blood level > 1.5ULN)

- Ongoing heavy alcohol consumption (>100g alcohol/day)

- Administration of any concomitant treatment likely to interfere with clonidine

- Known hypersensitivity to clonidine, history of allergy or intolerance to milk proteins or any other component of the product

- Presence of severe or uncontrolled depression

- Pregnant or breast-feeding women

- Inability to give informed consent or comply with study requirements

- Unable or unwilling to comply with follow-up visits

- Participation to a clinical trial within 30 days prior to randomization and during the entire duration of the study

Addresses

■ **Primary Sponsor**

BioAlliance Pharma SA

Primary Sponsor

BioAlliance Pharma SA

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Contact for Scientific Queries**

BioAlliance Pharma
Bérangère Vasseur, MD

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Contact for Public Queries**

René-Jean Bensadoun, MD

Telephone: **+33(0)5.49.44.44.93**
Fax: **[---]***
E-mail: **rene-jean.bensadoun at chu-poitiers.fr**
URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.

- Translation on version: 17

- Last processed date by ClinicalTrials.gov: 2013/12/01

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.