

# Protocol for Composite Facial Allograft Transplantation

**This study is currently recruiting participants.**

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<b>Sponsor:</b>	<b>Cleveland Clinic</b>
<b>Participating Sites:</b>	<b>Cleveland Clinic, Cleveland, OH</b>
<b>ClinicalTrials.gov Identifier:</b>	<b>NCT01269164</b>

## **Purpose**

The purpose of this study is to apply human facial allograft transplant to the subjects with severe facial deformities or disfigurements in order to provide adequate coverage, aesthetic appearance and functional outcome.

## **Objectives**

### Primary Objective:

Evaluate the success of the face transplant. Demonstrate stable engraftment and restoration of facial skin/bone coverage and sensory-motor function in recipients of composite tissue allografts of vascularized skin, bone, and soft tissue augments (nose, ear, lips, eyelids, etc) under standard immunopression protocol.

### Secondary Objective:

Evaluate tolerogenic properties of the immunosuppression protocol. Characterize tolerogenic properties of our immunosuppression protocol, by monitoring of donor specific chimerism and presence of T regulatory cells in the face allograft transplant recipients.

## **Study Design**

The human scalp and face define two important body units, both functionally and aesthetically. Traumatic deformities of the head and neck region resulting from burn injuries, gunshot wounds, or ablative tumor surgeries may involve the defect of the skin, subcutaneous tissue, muscle or the combination of all these elements. In most cases, the ideal reconstruction is very difficult to achieve. Sometimes, a major part of face along with the ear or the nose may be involved. The extensive scalp loss due to burn or avulsion injury is another deforming and psychologically debilitating condition presenting as a major reconstructive challenge. An ideal reconstructive procedure should replace the missing tissues and restore the motor and sensory function. Traditional reconstructive procedures of facial deformities involve skin grafting, local flap applications, tissue expansion, and prefabrication as well as free tissue transfers. The primary goal during facial reconstruction is restoration of the function and aesthetic appearance. To obtain satisfactory results, missing parts should be replaced only by tissues of the same color and texture. The purpose of this study is to apply human facial allograft transplant to the subjects with severe facial deformities or disfigurements in order to provide adequate coverage, aesthetic appearance and functional outcome.

## **Eligibility**

### Inclusion Criteria:

1. Subject must be willing to sign the informed consent and agree to all follow up procedures, including the realistic understanding of the impact of face allotransplantation on their lifestyle
2. Subjects will be evaluated by plastic surgeon to assess indications for facial allotransplantations based on severity and complexity of facial deformity
3. Subjects ages 18-60.
4. Subject must be willing to undergo a psychiatric and social services pre-transplantation evaluation
5. Subject must be willing to undergo major face surgery
6. Subject must be a candidate for general anesthesia
7. Subjects must be willing to comply with post transplant physical therapy.

8. Subject must be willing and able to receive potent drugs that induce immunosuppression and follow the infection prophylaxis protocol
9. Subject must be willing to receive standard vaccinations such as influenza, pneumococcus, and hepatitis B.
10. Subjects must be a non-smoker.
11. Subjects must be free of malignant tumors for 2-5 or more years with the exception of skin cancer.

**Exclusion Criteria:**

1. Subject that shows history of persistent non-compliance
2. Findings of the psychiatric evaluation that may indicate non-compliance or mental instability
3. Presence of an active infection including Human Immunodeficiency Virus, mycobacteria, hepatitis B, and hepatitis C
4. Presence of an occult infection for example, dental abscess, UTI, tuberculosis, or history of systemic/occult infection within 3 months of surgery
5. Any current Chemical Dependency including alcohol
6. Subjects at high risk for the recurrence of malignancy with the exception of certain skin cancers
7. Any diagnosis that the qualifying plastic surgeon feels would put the subject at high risk for the surgical procedure of face transplantation
8. Subjects who do not have adequate donor sites for skin grafting in the event of post transplant flap failure

**Enrollment Information**

Estimated Enrollment: 2

Study Start Date: July 2010

Estimated Completion Date: July 2015

**Contacts**

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