

Registry of Patients With a Diagnosis of Spinal Muscular Atrophy (SMA)

Last Update: Jan 31, 2025

A Prospective, Long-Term Registry of Patients With a Diagnosis of Spinal Muscular Atrophy (SMA)

ClinicalTrials.gov Identifier:

[NCT04174157](#)

Novartis Reference Number:COAV101A12001

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All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

Spinal muscular atrophy (SMA) is a neurogenetic disorder caused by a loss or mutation in the survival motor neuron 1 gene (SMN1) on chromosome 5q13, which leads to reduced SMN protein levels and a selective dysfunction of motor neurons. SMA is an autosomal recessive, early childhood disease with an incidence of 1:10,000 live births. SMA is the leading cause of infant mortality due to genetic diseases.

The purpose of this registry is to assess the long term outcomes of patients with SMA in the context of advances in treatment options and also to characterize and assess long-term safety and effectiveness of OAV-101. This is a prospective, multi center, multinational, non-interventional observational study. All patients will be managed according to the clinical site's normal clinical practice, i.e., the diagnostic and clinical treatment/practice process that a clinician chooses according to their clinical judgement for an SMA patient. Clinical care will not be driven by the protocol. No additional visits or investigations will be performed beyond normal clinical practice. Patients will be followed for 15 years from enrolment or until death, whichever is sooner.

Condition

Spinal Muscular Atrophy (SMA)

Overall Status

Recruiting

Number of Participants

700

Start Date

Sep 25, 2018

Gender

All

Age(s)

- (Child, Adult, Older Adult)

Interventions

Other

Prospective observational registry

This prospective observational registry will assess long-term outcomes of patients with a diagnosis of SMA.
Drug

Zolgensma

Zolgensma will be given to patients as per normal clinical practice and clinical care will not be mandated by the protocol. As such, the decision to prescribe Zolgensma is separate from the decision to include the patient in this study

Eligibility Criteria

Inclusion Criteria:

- * Patients treated with OAV-101 with a genetically confirmed diagnosis of SMA regardless of the date of diagnosis.
- * Appropriate consent/assent has been obtained for participation in the registry

Exclusion Criteria:

- Currently enrolled in an interventional clinical trial involving an investigational medicinal product to treat SMA.

Note: Patients who are participating in a Compassionate Use Program (CUP) for OAV-101 (Zolgensma) such as a Managed Access Program (MAP), an Expanded Access Program (EAP), Single Patient Investigational New Drug (IND) (SPI) or Named Patient Program (NPP) are eligible to enroll in the registry regardless of the date of a genetic or clinical diagnosis of SMA.

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