

Plan Overview

A Data Management Plan created using DMPTool

DMP ID: <https://doi.org/10.48321/D1SC7J>

Title: AntiVEGF therapy vs Ozurdex for the treatment of Diabetic Macular Edema

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Funder: National Institutes of Health (nih.gov)

Funding opportunity number: PA-20-183

Grant: 1R01EY01336001

Template: NIH-GEN: Generic (Current until 2023)

Project abstract:

Diabetic Macular Edema (DME) is the leading cause of vision loss in patients with diabetes due to accumulation of fluid in the retina. The accumulation of fluid in the retina is believed to be caused by upregulation of VEGF in retina. AntiVEGF therapy is the gold standard for the treatment of DME. Although effective, approximately two thirds of patients treated DME do not respond to antiVEGF therapy and continue to lose vision, suggesting an underlying mechanism. Recent studies suggest that inflammation plays a key role in development of DME. Ozurdex is a multi-potent corticosteroid that inhibits VEGF and inflammatory cytokines but, the use of Ozurdex for the treatment of DME has yet to be investigated. To determine whether Ozurdex is an effective treatment for DME, 100 randomized patients will receive monthly injections of Ozurdex or antiVEGF therapy for 12 months. The data collected in this study will serve as a pivotal dataset for future investigators to determine the appropriate course of treatment for the management of DME.

Start date: 09-07-2021

End date: 09-07-2022

Last modified: 05-10-2023

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AntiVEGF therapy vs Ozurdex for the treatment of Diabetic Macular Edema

Data sharing plan

How do you plan to provide access to your data?

Access will be publicly available provided through clinicaltrials.gov under the results tab.

When will you make the data available?

Data will be available within 6 months of the project end date.

Which archive/repository/central database have you identified as a place to deposit data?

Clinicaltrials.gov

Will a data-sharing agreement be required?

No because data will be accessible by the public.

What metadata/documentation will be submitted alongside the data?

Title: AntiVEGF therapy vs Ozurdex for the treatment of diabetic macular edema

Creator: Jones, Wendell

Identifier: 8265

Date: 2021-09-01 (start), 2021-09-01-2022 (end),

Method: Randomized patients will receive monthly ocular injections into the back of the eye of antiVEGF or Ozurdex. After each injection patients will return 29 days later for visual acuity measurements. Visual acuity improvement or decrease will be determined using a Snellen chart. Number of letters of improvement or decline from previous study visit baseline will be recorded in the EDC capture system.

Processing: Data will be collected using a EDC. Data will then be extracted from EDC into excel to conduct analysis. Data will be transformed into txt format and stored in registry.

Source: pub.med.gov

Funder: National Eye Institute (NEI)

Subject: antiVEGF, Ozurdex, Ophthalmology, diabetic macular edema, visual acuity

Language: English

Variables: patient ID, date, sex, age, treatment, score, Ozurdex, antiVEGF

File inventory: NWPalaceTR.WRL

File format: NCT

Necessary software: excel

Rights: read-only

Access info: Data can be accessed at clinicaltrials.gov

What file formats will you use for your data, and why?

PDF/A

What transformations will be necessary to prepare data for preservation/data sharing?

patient names will be de-identified in order to protect patient confidentiality.

Do you need funding for the implementation of this data sharing plan?

No

Planned Research Outputs

Text - "AntiVEGF therapy vs Ozurdex for the treatment of Diabetic Macular Edema"

Randomized patients with DME treated monthly with Ozurdex experienced a statistically significant improvement in visual acuity and resolution of fluid compared to patients treated with antiVEGF therapy. Patients treated with Ozurdex experienced a 10 letter gain at month 12 compared to baseline while patients on antiVEGF therapy experienced a 5 letter gain at month 12 compared to baseline.

Planned research output details

Title	Type	Anticipated release date	Initial access level	Intended repository(ies)	Anticipated file size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
AntiVEGF therapy vs Ozurdex for the treatment of D ...	Text	2022-10-07	Open	ClinicalTrials.gov	1 MB	Creative Commons Attribution Non Commercial 4.0 International	DataCite Metadata Schema	Yes	No