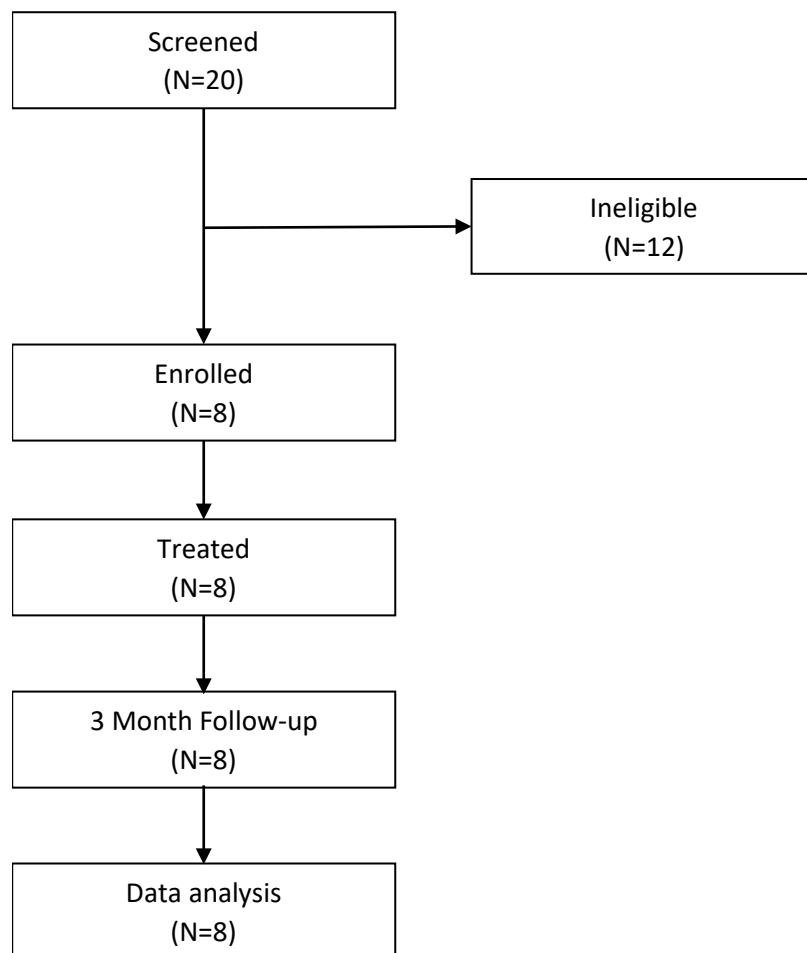


## PARTICIPANT FLOW



## **BASELINE CHARACTERISTICS**

Gender	Male	8
	Female	0
Age [years]	Mean (SD)	29.5 (7.7)
	Median	28.0
	Range	21; 47
Height [cm]	Mean (SD)	172 (7)
	Median	173
	Range	160; 180
Weight [kg]	Mean (SD)	64.0 (9.5)
	Median	62.2
	Range	54.0; 86.4
BMI	Mean (SD)	21.7 (2.2)
	Median	21.3
	Range	19.8; 26.7

**OUTCOME MEASURES****Pharmacokinetic Parameters - Imlifidase**

PK Parameter		N=8
C <sub>max</sub> (µg/mL)	n	8
	Arithmetic mean (SD)	5.2 (1.2)
AUC (h×µg/mL)	n	4
	Arithmetic mean (SD)	166 (138)
T <sub>max</sub> (h)	n	8
	Median	0.27
	Min; max	0.27; 0.28
t <sub>½</sub> (h) initial phase (α)	n	4
	Harmonic mean	3.3
t <sub>½</sub> (h) elimination phase (β)	n	4
	Harmonic mean	95
CL (mL/h/kg)	n	4
	Arithmetic mean (SD)	2.5 (1.9)
V <sub>z</sub> (L/kg)	n	4
	Arithmetic mean (SD)	0.36 (0.23)
V <sub>ss</sub> (L/kg)	n	4
	Arithmetic mean (SD)	0.25 (0.14)

**Pharmacodynamic profile - IgG concentration following investigational drug administration (N=8)**

The PD profile after administration of a single dose of imlifidase to the subjects in this clinical trial looks similar to that in other studies with imlifidase.

**Immunogenicity - Concentration of anti-drug antibodies (mg/L) (N=8)**

The immunogenicity (i.e. concentration of anti-drug antibodies) after administration of a single dose of imlifidase to the subjects in this clinical trial looks similar to that in other studies with imlifidase.

**IgG and IgG-fragments in urine (N=8)**

The results show similar profiles of IgG/Ig-fragment in urine after a single dose of imlifidase as in other studies with imlifidase.

**Safety**

None of the 11 reported adverse events (AEs) in this clinical trial were deemed to be a serious adverse event (SAE).

**Adverse events by MedDRA system organ class and preferred term**

<b>SOC</b> <b>Preferred Term</b>	<b>N=8</b> <b>n (%) E</b>
<b>Any AE</b>	<b>6 (75) 11</b>
<b>General disorders and administration site conditions</b>	<b>1 (13) 2</b>
Catheter site bruise	1 (13) 1
Fatigue	1 (13) 1
<b>Infections and infestations</b>	<b>1 (13) 1</b>
Covid-19	1 (13) 1
<b>Musculoskeletal and connective tissue disorders</b>	<b>2 (25) 2</b>
Pain in extremity	1 (13) 1
Neck pain	1 (13) 1
<b>Nervous system disorders</b>	<b>3 (38) 3</b>
Hypoaesthesia	3 (38) 3
<b>Respiratory, thoracic, and mediastinal disorders</b>	<b>1 (13) 1</b>
Throat tightness	1 (13) 1
<b>Skin and subcutaneous tissue disorders</b>	<b>1 (13) 1</b>
Rash maculo-papular	1 (13) 1
<b>Vascular disorders</b>	<b>1 (13) 1</b>
Hot flush	1 (13) 1

Abbreviations: AE=adverse event; N=number of subjects exposed; n=number of subjects with AE; %=n/N; E=number of events