

ULLTRA Study - Monthly Missing Data Report

Report date: 2025-09-04 Reporting period: 2024-01-26 - 2025-09-04

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Figure 1. Study Enrollment Summary

- Total enrollment: 94
- Total randomized: 57
- Participants who reached V5: 48 (84%)
- Participants who reached V9: 46 (81%)
- Participants who reached FU1: 43 (75%)
- Participants who reached FU2: 28 (49%)
- Participants who reached V10: 30 (53%)

Note: U081 skipped V5, but completed V9 before discontinuation of the study as a withdrawn visit.

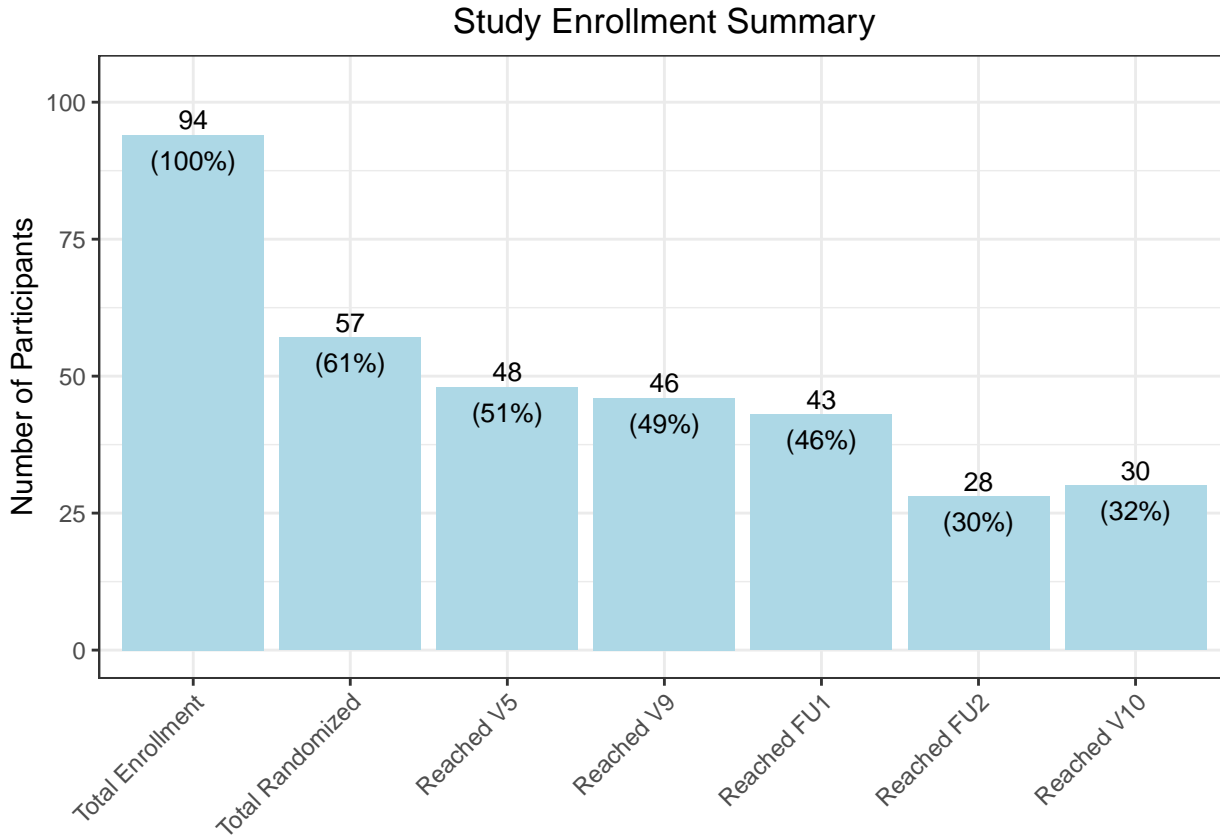


Table 1. Participant Visit Status

Participant ID	Randomized	V5 Completed	V9 Completed	V10 Completed	Status
U001	Yes	Yes	Yes	Yes	Completed
U003	Yes	Yes	Yes	Yes	Completed
U007	Yes	Yes	Yes	Yes	Completed
U011	Yes	Yes	Yes	Yes	Completed
U012	Yes	Yes	Yes	Yes	Completed
U014	Yes	Yes	Yes	Yes	Completed
U018	Yes	Yes	Yes	Yes	Completed
U020	Yes	Yes	Yes	Yes	Completed
U022	Yes	No	No	No	Withdrew consent
U027	Yes	Yes	Yes	Yes	Completed
U030	Yes	Yes	Yes	Yes	Completed
U035	Yes	No	No	No	Ineligible after randomization
U045	Yes	Yes	Yes	Yes	Completed
U048	Yes	Yes	Yes	Yes	Completed
U050	Yes	Yes	Yes	Yes	Completed
U051	Yes	Yes	Yes	Yes	Completed
U053	Yes	Yes	Yes	Yes	Completed
U062	Yes	Yes	Yes	Yes	Completed
U070	Yes	Yes	Yes	Yes	Completed
U073	Yes	Yes	Yes	Yes	Completed
U078	Yes	Yes	Yes	Yes	Completed
U079	Yes	Yes	Yes	Yes	Completed
U081	Yes	No	No	No	Investigator's opinion not to continue
U085	Yes	Yes	Yes	Yes	Completed
U086	Yes	Yes	Yes	Yes	Completed
U093	Yes	Yes	Yes	Yes	Completed
U099	Yes	Yes	Yes	Yes	Completed
U102	Yes	Yes	Yes	Yes	Completed
U107	Yes	Yes	Yes	Yes	Completed
U108	Yes	Yes	Yes	Yes	Completed
U109	Yes	Yes	Yes	Yes	Completed
U110	Yes	Yes	Yes	No	Active in study
U114	Yes	Yes	Yes	Yes	Completed
U120	Yes	Yes	Yes	Yes	Completed
U125	Yes	Yes	Yes	No	Active in study
U127	Yes	No	No	No	Investigator's opinion not to continue
U129	Yes	Yes	Yes	No	Active in study
U131	Yes	Yes	Yes	No	Active in study
U135	Yes	No	No	No	Withdrew consent
U142	Yes	Yes	Yes	No	Active in study
U146	Yes	Yes	Yes	No	Active in study
U156	Yes	Yes	Yes	No	Active in study
U158	Yes	Yes	Yes	No	Active in study
U161	Yes	Yes	Yes	No	Active in study
U169	Yes	Yes	Yes	No	Active in study
U170	Yes	Yes	Yes	No	Active in study
U175	Yes	Yes	Yes	No	Active in study
U179	Yes	Yes	Yes	No	Active in study
U182	Yes	Yes	Yes	No	Active in study
U187	Yes	Yes	Yes	No	Active in study
U188	Yes	No	No	No	Active in study
U189	Yes	Yes	Yes	No	Active in study
U193	Yes	Yes	No	No	Active in study
U203	Yes	Yes	No	No	Active in study

U210	Yes	No	No	No	Active in study
U219	Yes	No	No	No	Active in study
U221	Yes	No	No	No	Active in study

Primary outcome:

- The Daily Symptom Diary (DSD) entries ≥ 4 in 7 days prior to V1 and V9

Secondary outcome:

- The Daily Symptom Diary (DSD) entries ≥ 4 in 7 days prior to V1 and V10
- The Pain, Enjoyment, General Activity (PEG) score obtained at V0, the 1- and 3-month follow-up assessments, and at V10.

Exploratory outcome:

- Pain intensity (JAW pain intensity) and range of motion in millimeters for unassisted and assisted mouth opening (Assisted/unassisted mouth opening).
- **Circulating cytokines in whole blood at V1, V5, and V9 (not included)**
- Pressure Pain Threshold (PPT) performed at V0, V5, V9, and V10.

Table 2. Outcome Data Summary

Visit	Total Expected (n%)	Completed (n%)	Awaiting (n%)	Incomplete (n%)
DSD entries ≥ 4 in 7 days prior to visit				
V1	57 (100%)	51 (89%)	5 (9%)	1 (2%)
V9	46 (81%)	41 (89%)	0 (0%)	5 (11%)
V10	30 (53%)	30 (100%)	0 (0%)	0 (0%)
PEG score				
V0	57 (100%)	52 (91%)	5 (9%)	0 (0%)
FU1	43 (75%)	43 (100%)	0 (0%)	0 (0%)
FU2	38 (67%)	28 (74%)	0 (0%)	10 (26%)
V10	30 (53%)	30 (100%)	0 (0%)	0 (0%)
JAW pain intensity				
V0	57 (100%)	52 (91%)	5 (9%)	0 (0%)
V5	48 (84%)	48 (100%)	0 (0%)	0 (0%)
V9	46 (81%)	45 (98%)	0 (0%)	1 (2%)
V10	30 (53%)	30 (100%)	0 (0%)	0 (0%)
Assisted/unassisted mouth opening				
V0	57 (100%)	52 (91%)	5 (9%)	0 (0%)
V5	48 (84%)	48 (100%)	0 (0%)	0 (0%)
V9	46 (81%)	45 (98%)	0 (0%)	1 (2%)
V10	30 (53%)	29 (97%)	0 (0%)	1 (3%)
Pressure pain threshold				
V0	57 (100%)	52 (91%)	5 (9%)	0 (0%)
V5	48 (84%)	48 (100%)	0 (0%)	0 (0%)
V9	46 (81%)	45 (98%)	0 (0%)	1 (2%)
V10	30 (53%)	29 (97%)	0 (0%)	1 (3%)

Notes:

- “Completed”: Data fully entered and verified
- “Awaiting”: Participant reached visit, data expected but not entered yet
- “Incomplete”: Visit missed or insufficient data collected (e.g., <4 DSDs)

Table 3. Incomplete Outcomes

ID	Incomplete Endpoint	Event
U219	DSD entries ≥ 4 in 7 days prior to visit	V1
U079	DSD entries ≥ 4 in 7 days prior to visit	V9
U108	DSD entries ≥ 4 in 7 days prior to visit	V9
U169	DSD entries ≥ 4 in 7 days prior to visit	V9
U175	DSD entries ≥ 4 in 7 days prior to visit	V9
U187	DSD entries ≥ 4 in 7 days prior to visit	V9
U001	PEG score	FU2
U003	PEG score	FU2
U007	PEG score	FU2
U011	PEG score	FU2
U012	PEG score	FU2
U014	PEG score	FU2
U018	PEG score	FU2
U020	PEG score	FU2
U027	PEG score	FU2
U099	PEG score	FU2
U179	JAW pain intensity	V9
U179	Assisted/unassisted mouth opening	V9
U011	Assisted/unassisted mouth opening	V10
U179	Pressure pain threshold	V9
U011	Pressure pain threshold	V10