

85 years and over	0
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Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino Not Hispanic or Latino			
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaskan Native Asian Black or African American Native Hawaiian or Other Pacific Islander White Other			

End point values	Placebo Cohort 1	MEDI0382 Cohort 1	Placebo Cohort 2	MEDI0382 Cohort 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	26	6	20
Units: Participants				
Baseline (ADA positive) (n=13, 26, 6, 20)	0	0	0	0
Day 29 (ADA positive) (n=13, 26, 6, 18)	0	4	0	1
Day 50 (ADA positive) (n=13, 25, 6, 18)	0	7	0	2
Follow-up Visit 2 (ADA positive) (n=13, 24, 6, 20)	1	6	0	6

Statistical analyses

No statistical analyses for this end point

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 26 (3.85%) 1	0 / 6 (0.00%) 0
Vessel puncture site haematoma subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 26 (3.85%) 1	0 / 6 (0.00%) 0
Reproductive system and breast disorders Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 26 (0.00%) 0	1 / 6 (16.67%) 1
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 26 (3.85%) 1	1 / 6 (16.67%) 1
Epistaxis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 26 (3.85%) 1	0 / 6 (0.00%) 0
Nasal obstruction subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 26 (0.00%) 0	1 / 6 (16.67%) 1
Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 26 (3.85%) 1	0 / 6 (0.00%) 0
Psychiatric disorders Loss of libido subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 26 (3.85%) 1	0 / 6 (0.00%) 0
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 26 (0.00%) 0	0 / 6 (0.00%) 0
Procedural nausea subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 26 (3.85%) 1	0 / 6 (0.00%) 0
Cardiac disorders			

Loss of libido subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all) Procedural nausea subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0 0 / 20 (0.00%) 0		
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Tremor subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1 4 / 20 (20.00%) 6 1 / 20 (5.00%) 5		
Blood and lymphatic system disorders Thrombocytopenia subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Eye disorders Visual impairment subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all) Abdominal pain	1 / 20 (5.00%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 July 2017	The original protocol was amended to modify exploratory objectives, clinical laboratory test, exclusion criteria, procedures, prohibited concomitant medications, reduction in blood volume, and to correct typographical errors.
17 October 2017	The protocol amendment 2 was made to modify the procedures, table footnotes, time frame for serious adverse events, updated with the definition of postmenopausal to correct a previous oversight, and clarification on maternal exposure.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported