



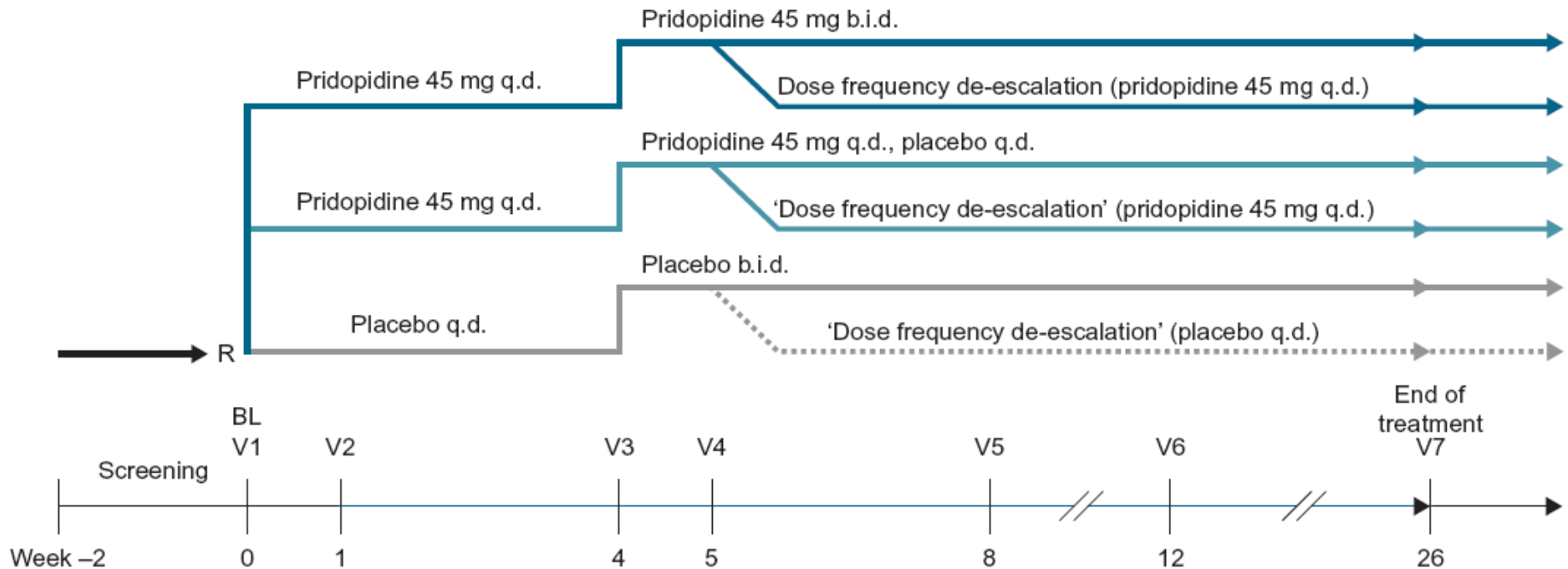
Huntexil® (pridopidine) in Huntington's Disease  
**The MermaiHD study – Top-line results**

**NEUROSEARCH**

# The MermaiHD study - Design



- A 26 weeks randomized, double-blinded, parallel-group study, comparing Huntexil<sup>®</sup> 45 mg once daily or twice daily versus placebo for the symptomatic treatment of HD

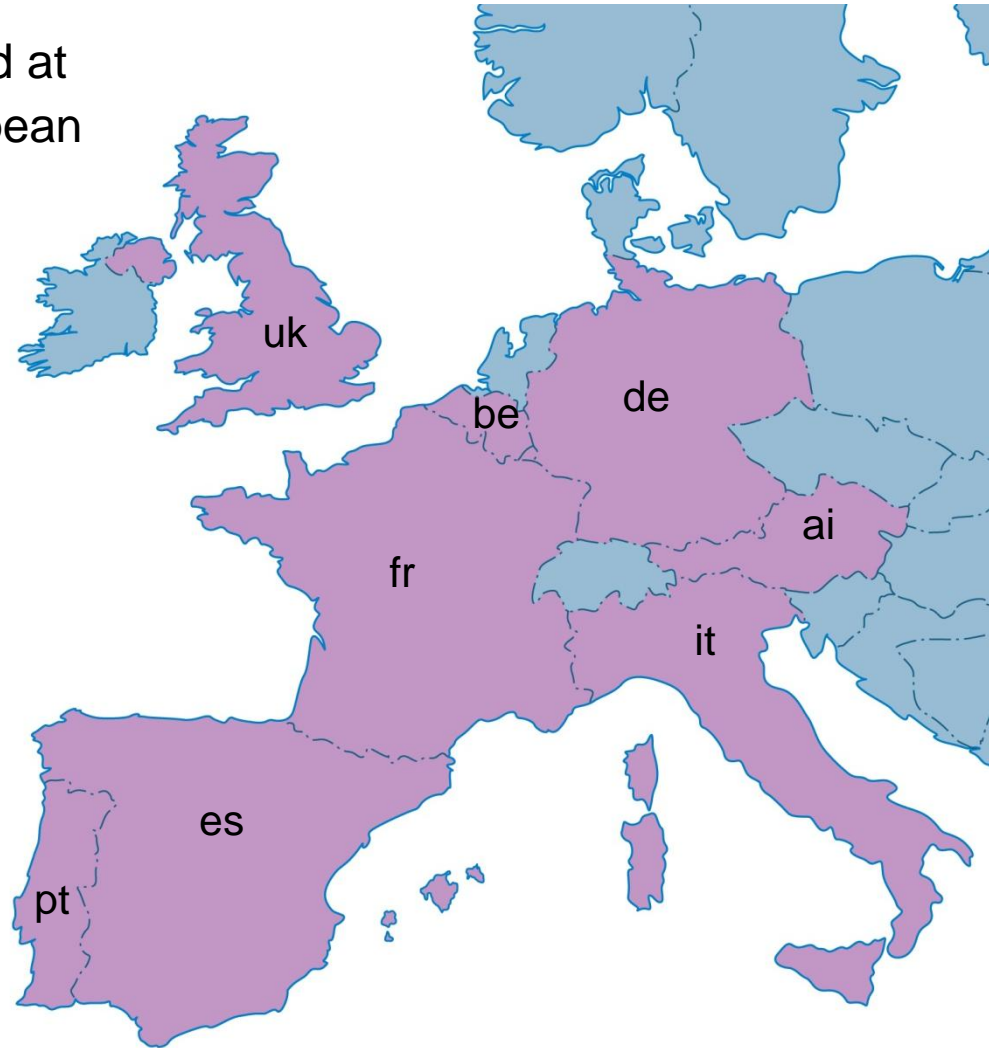


BL = baseline; b.i.d., = twice daily; q.d. = once daily; R = randomization; V = visit.

# The MermaiHD study - Participating countries



- The study was conducted at 32 centres in eight European countries



# Study population – Characteristics



- Aged between 30 and 86 years, mean = 50.6 years
- 215 male, 222 female
- Anti-psychotic medication
  - On: 190 patients (43.5%)
  - Not on: 247 patients (56.5%)
- Mean CAG repeat = 44.7 (between 36 and 63)
- Baseline mean time since diagnosis = 4.8 years (between 0 and 20 years)

# Demographics



	Placebo	Huntexil® 45mg QD	Huntexil® 45mg BID
Age (years)	49.1	51.0	51.8
Weight (kg)	68.2	67.2	69.8
Time since diagnose (mo) (All)	58.7	55.0	61.8
(No anti-psychotics)	56.5	45.1	60.3
(Anti-psychotics)	61.5	68.1	63.7
Anti-psychotic treatment (All)	144	148	145
(No anti-psychotics)	80	84	83
(Anti-psychotics)	64	64	62
Gender (All)	144	148	145
Female (%)	53	55	44

# The MermaiHD study - Compliance and safety

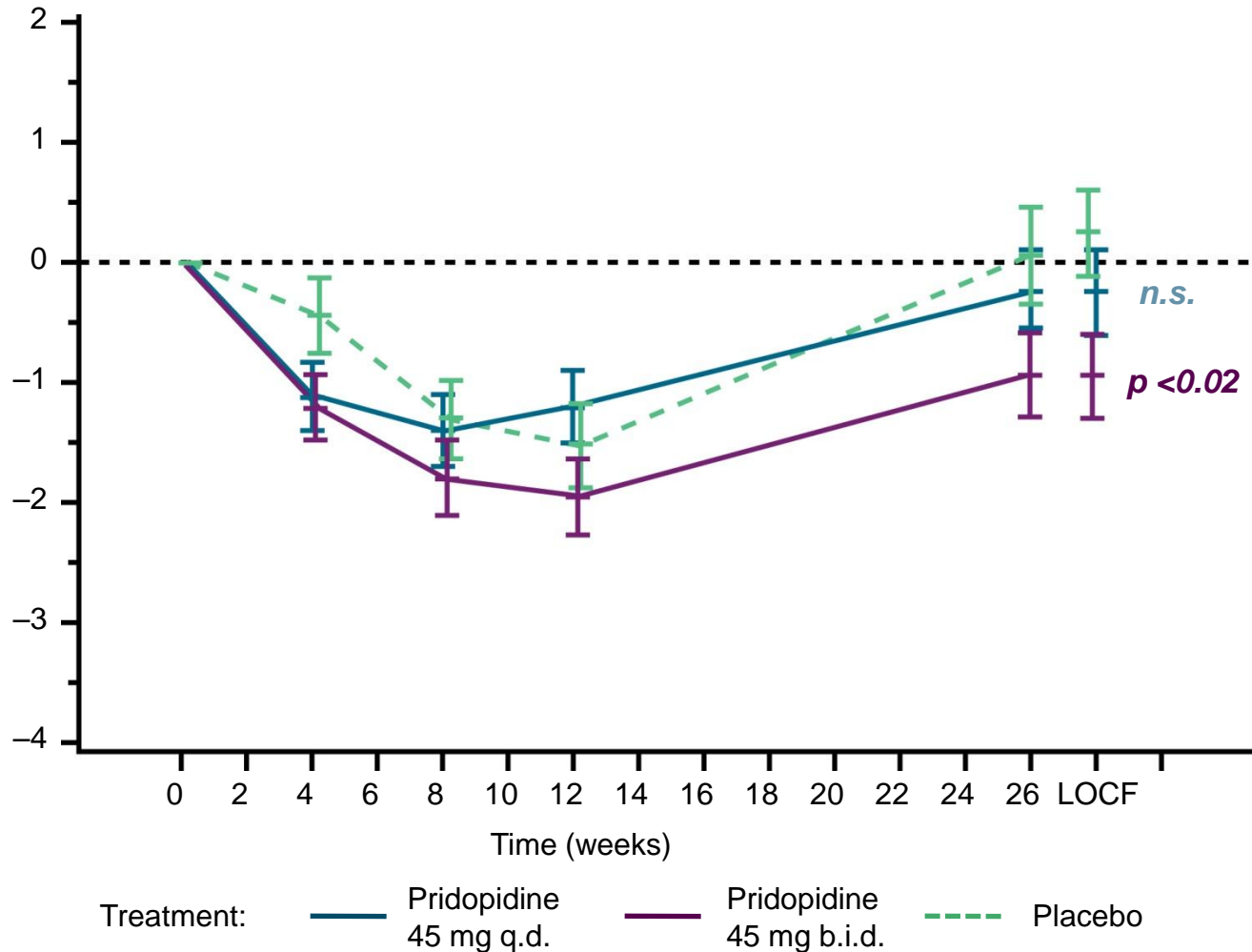


- Randomised patients, ITT population = 437 (100%)
  - Placebo= 144; 45 mg QD= 148; 45 mg BID= 145
- Completers: 92%
  - Placebo= 129 (90%); 45 mg QD= 143 (97%); 45 mg BID= 131 (90%)
- Withdrawals due to AE = 17 (4%)
  - Placebo= 8 (6%); 45 mg QD= 2 (1%); 45mg BID= 7 (5%)
- AEs similar across study arms
- Completers in full compliance, PP population = 82% (357)

# Primary endpoint: Significant improvement of voluntary movements (mMS)



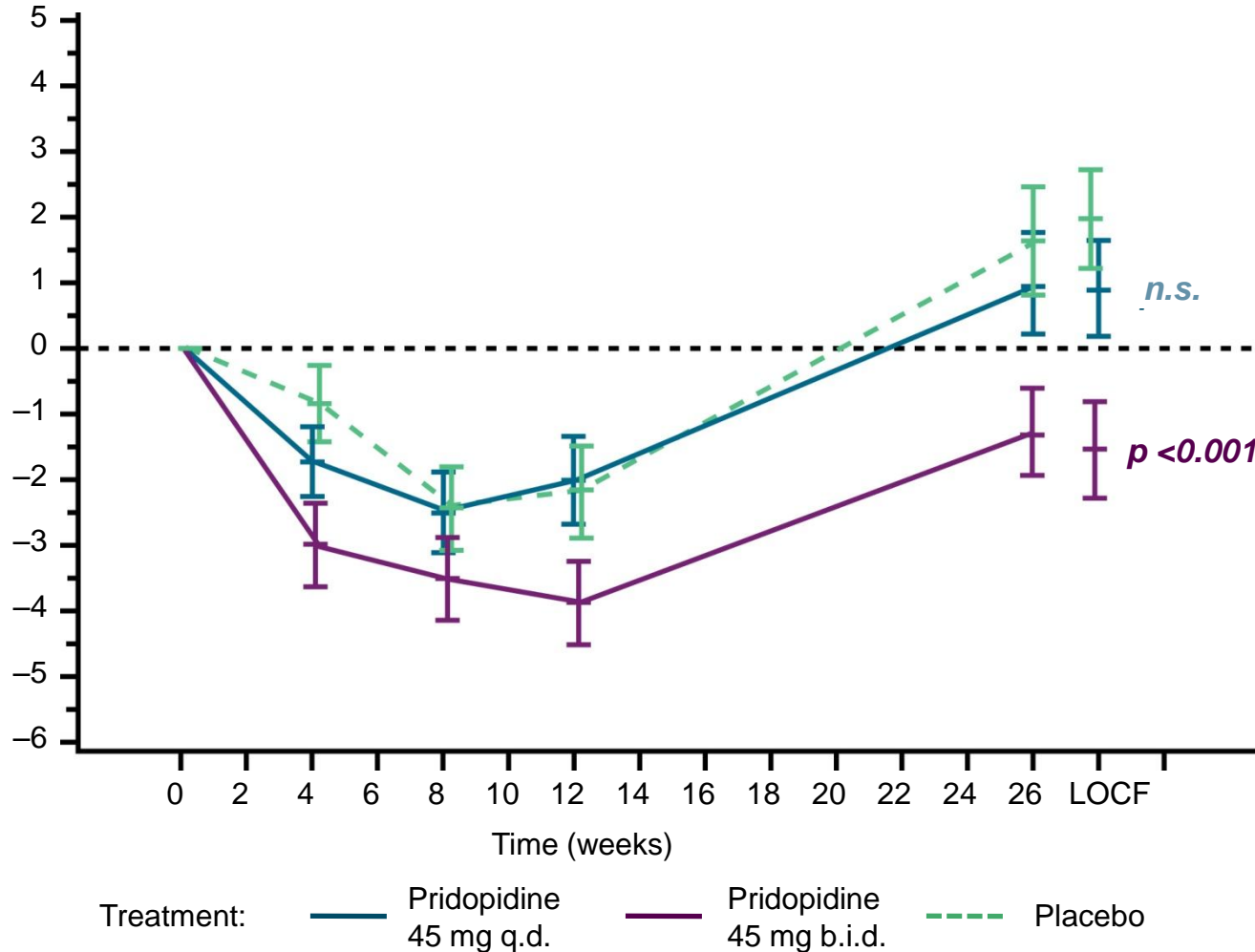
Full analysis set (ITT population)



# Significant improvement of global motor function (TMS)



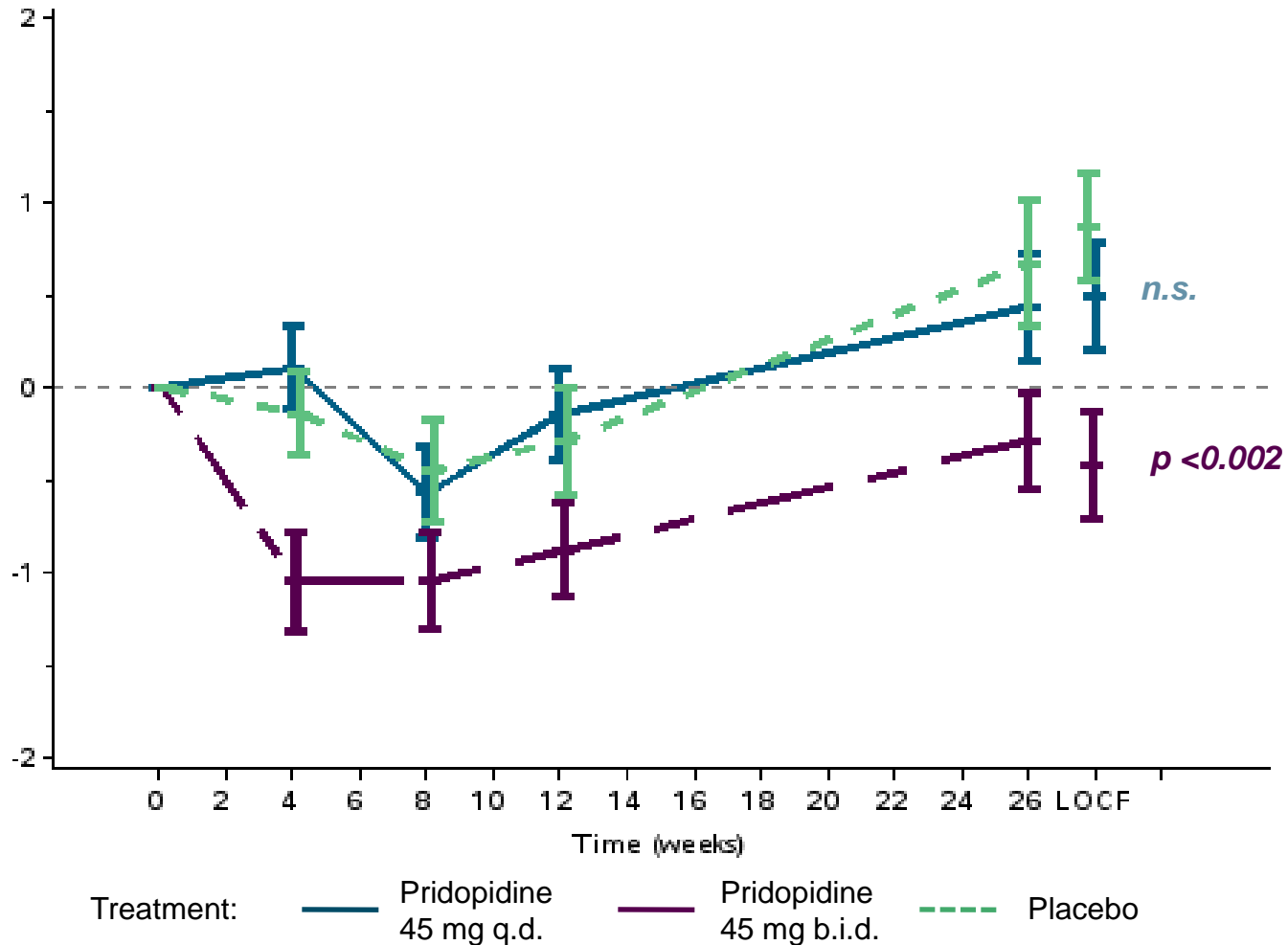
Full analysis set (ITT population)



# Significant improvement of Eye movements



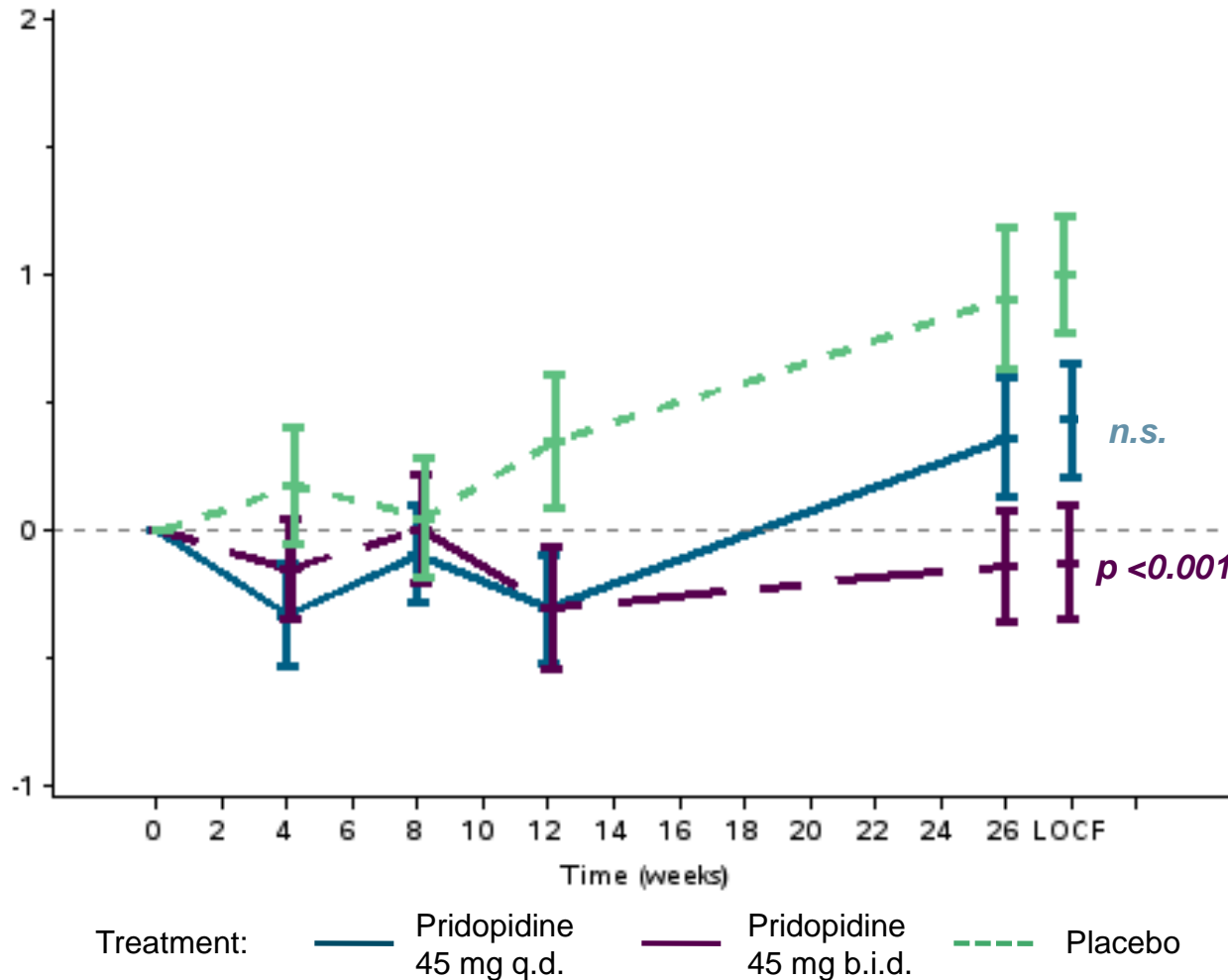
Full analysis set (ITT population)



# Significant improvement of Dystonia



Full analysis set (ITT population)



# Efficacy results consistent across ITT and PP



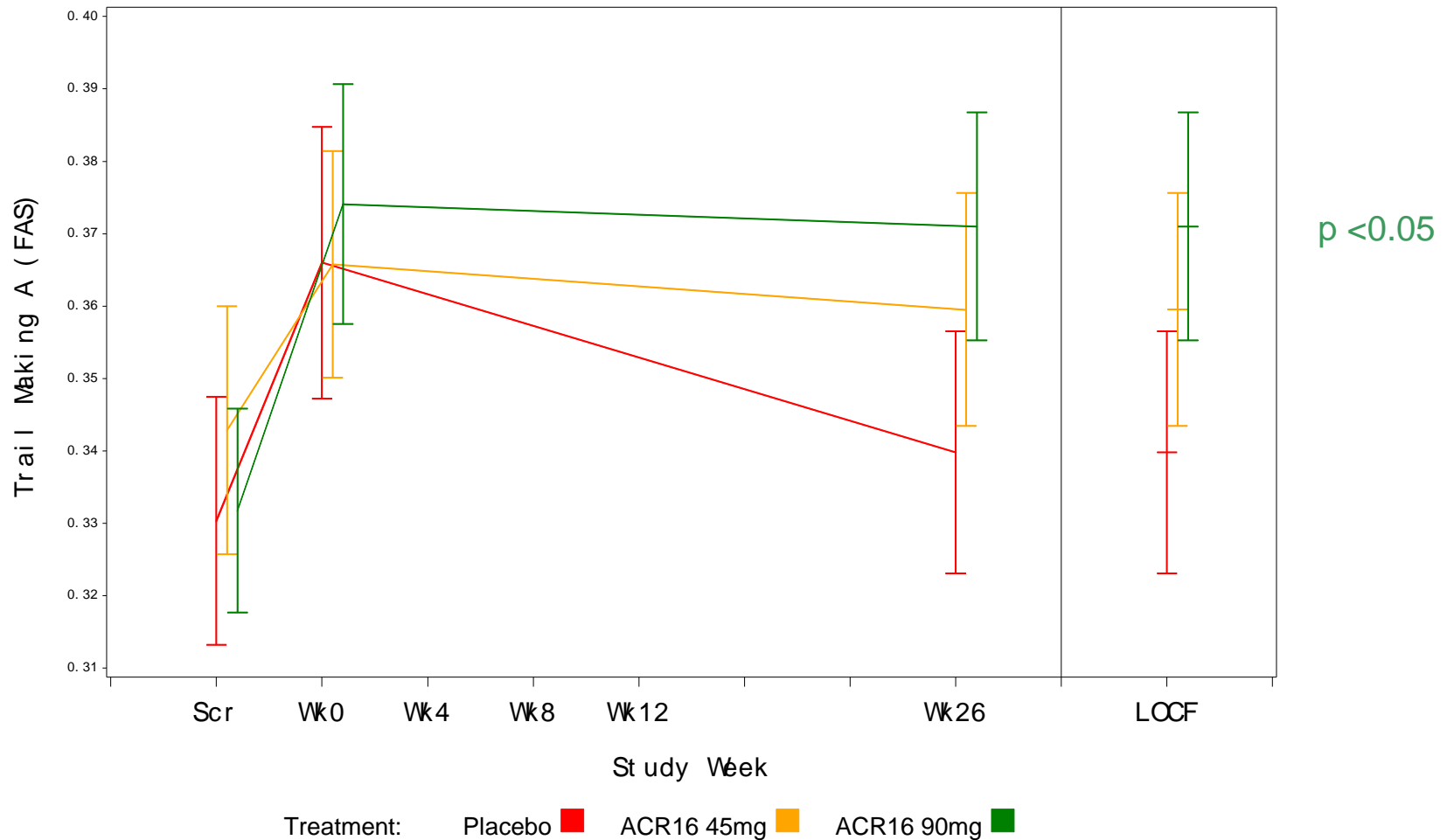
- ITT population = 437 randomised HD patients
- PP population = 357 patients, who completed the study according to the protocol or with minor protocol violations

<b>Motor scale</b>	<b>Significance level for the ITT population</b>	<b>Significance level for the PP population</b>
Modified Motor Score, mMS	$p < 0.02$	$p < 0.005$
Total Motor Score, TMS	$p < 0.001$	$p < 0.005$
Eye movements	$p < 0.002$	$p < 0.02$
Dystonia	$p < 0.001$	$p < 0.01$

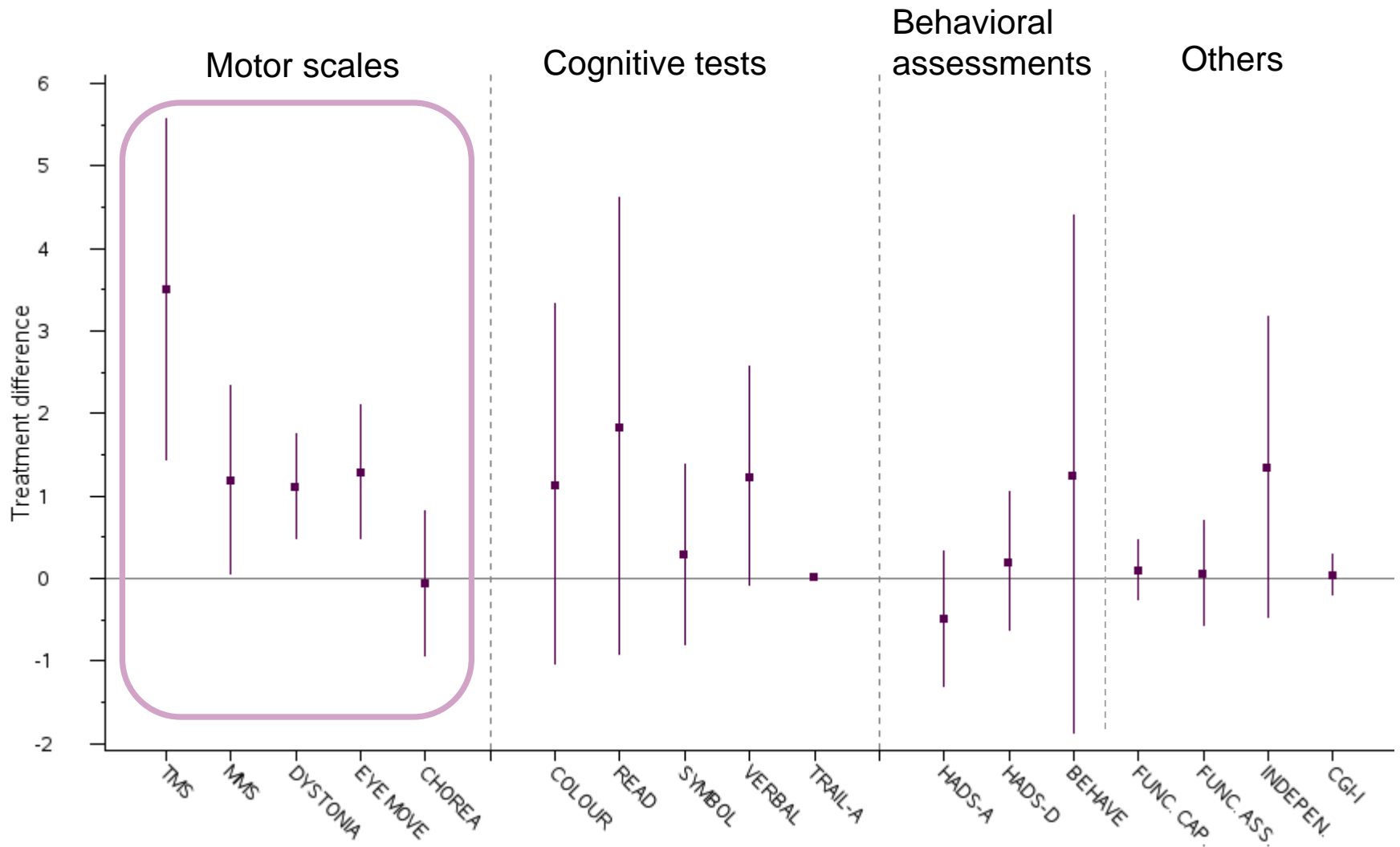
# Cognitive endpoint - Improved trail making



## Significantly improved trail making



# Overview of symptoms assessments



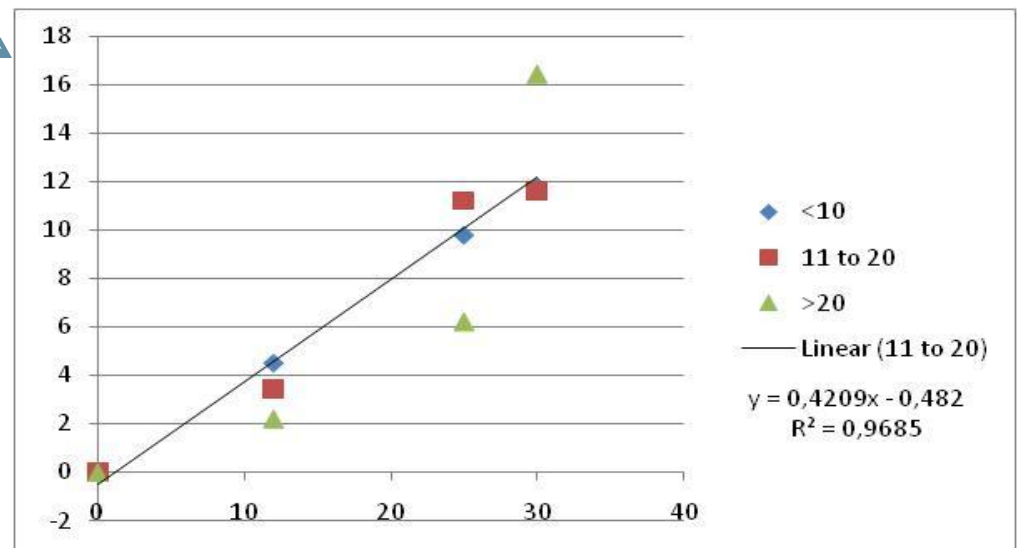
# The MermaiHD study results; Clinical relevance of treatment effect



## ➤ Huntexil®: Absolute treatment effect vs. disease progression\*

	Scale improvement	Corresponding progression
TMS	~3.5	9 - 10 months
mMS	~1	6 - 7 months
Eye movements	~1	15 - 18 months
Dystonia	~1	15 - 18 months

\* Based on the CareHD data base



# Conclusions from the MermaiHD study



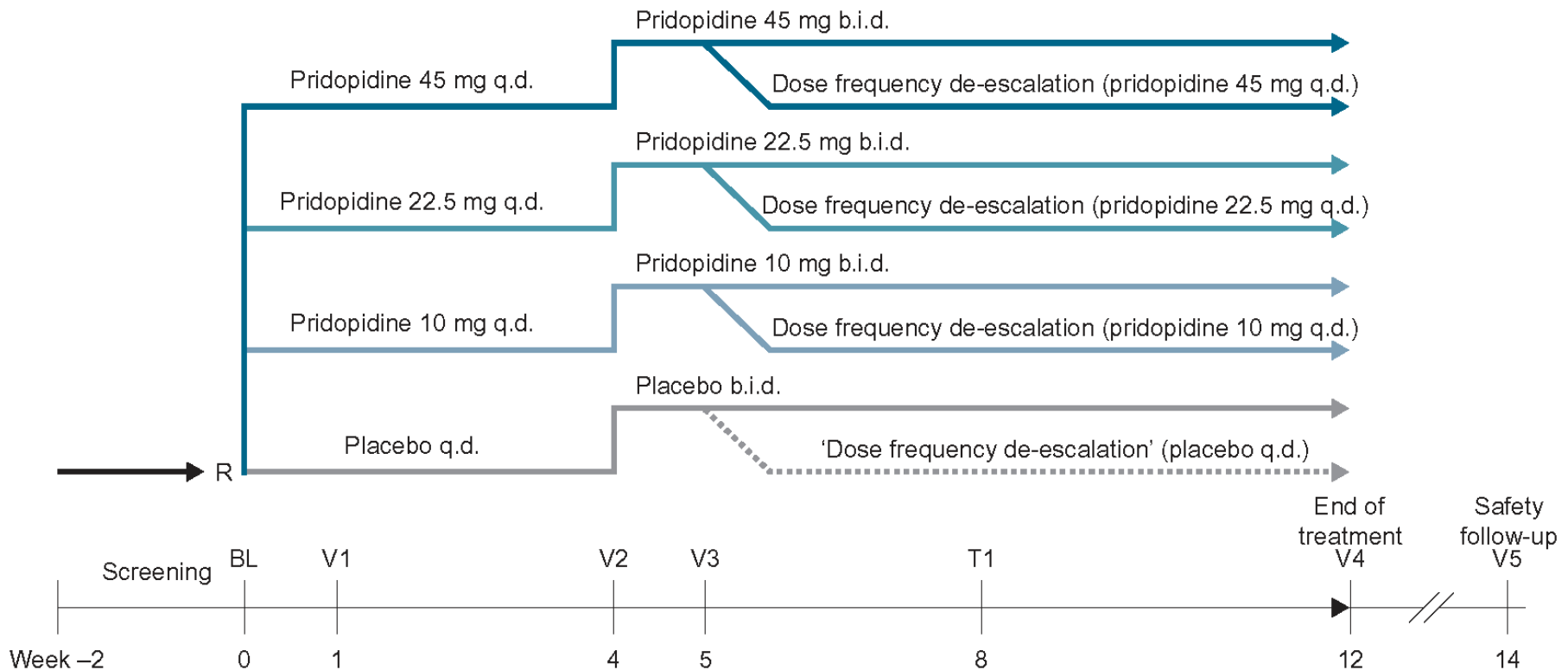
## In the MermaiHD study, Huntexil<sup>®</sup> has demonstrated to

- Significantly improve motor functions
  - Significant effect on both voluntary and involuntary disease symptoms
  - Translating into an estimated ½ to 1½ years of disease progression set-back
  
- No "therapeutic" disadvantages
  - No worsening of any disease signs or symptoms
  - No increased adverse events
  
- Results confirmed in patients both on and not on neuroleptic treatment
  
- Further in-depth analysis of the results is ongoing

# The HART study - Design



- A 12 week randomized, double-blinded, parallel-group study, comparing treatment with Huntexil® 45 mg once daily or twice daily versus placebo for the symptomatic treatment of HD



BL = baseline; b.i.d.,= twice daily; q.d. = once daily; R = randomization; V = visit; T = telephone contact.

# Huntexil<sup>®</sup> - Commercial route



- Further results expected through 2010
  - The HART study: Data from 3 months blinded study expected in H2 2010
  - MermaiHD: Data from open-label extension study (12 months) in H2 2010
  
- Planning for registration (MAA/NDA)
  - Based on results from total pivotal programme throughout 2010
  - Dialogue with regulatory authorities to be initiated after 6 months MermaiHD study results
  
- Other initiatives
  - Cost-of-illness study ongoing in major markets to support the overall benefit of Huntexil<sup>®</sup>
  - Named Patient Programme – potential launch in Europe in H1 2010
  - Clinical publication strategy

**Huntexil<sup>®</sup> – Aiming for market registration as fast as possible**



For more information, please visit [www.neurosearch.com](http://www.neurosearch.com) or write  
to [investor@neurosearch.dk](mailto:investor@neurosearch.dk)

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