

Huntexil® (pridopidine) in Huntington's Disease

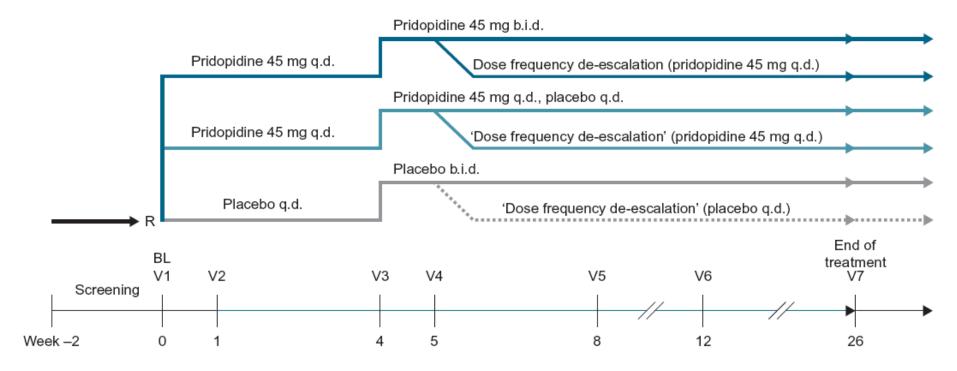
The MermaiHD study – Top-line results

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The MermaiHD study - Design



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



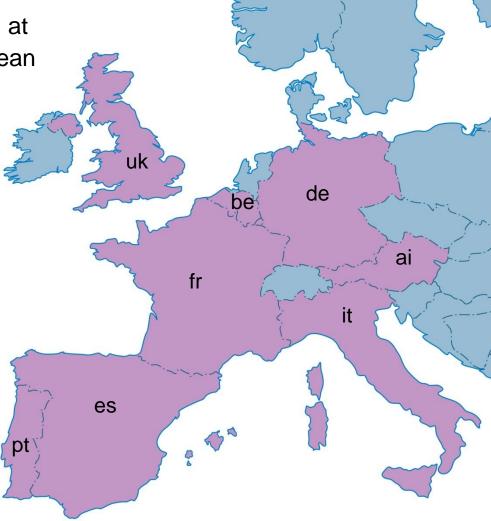
BL = baseline; b.i.d.,= twice daily; q.d. = once daily; R = randomization; V = visit.

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

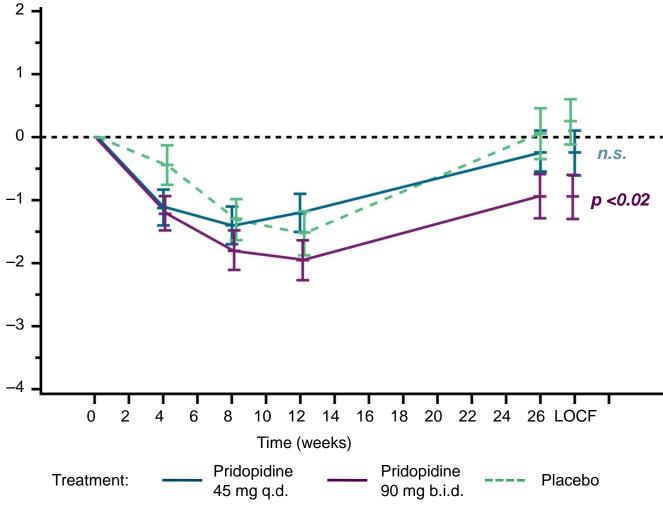
The MermaiHD study - Compliance and safety



- ➤ 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%)
- \rightarrow Withdrawals due to AE = 17 (4%)
 - Placebo= 8 (6%); 45 mg QD= 2 (1%); 45 mg BID= 7 (5%)
- ➤ AEs similar across study arms
- ➤ Completers in full compliance, PP population = 82% (357)

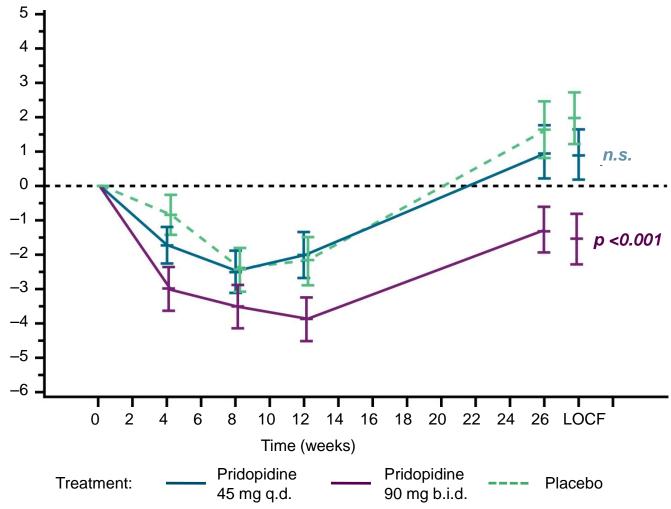
Primary endpoint: Significant improvement of voluntary movements (mMS)





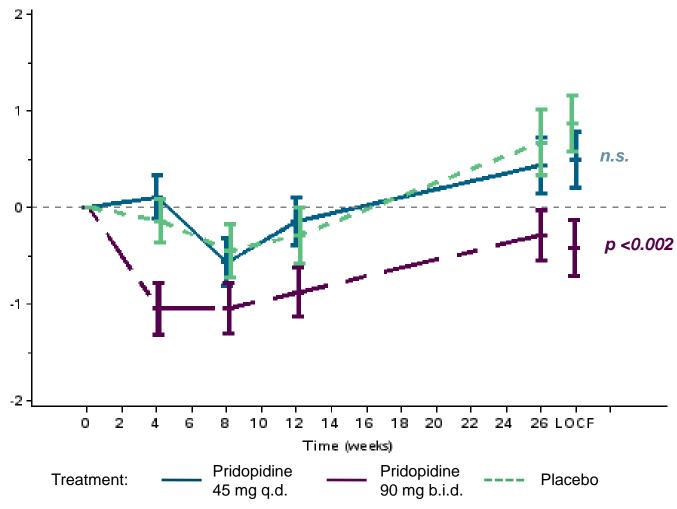






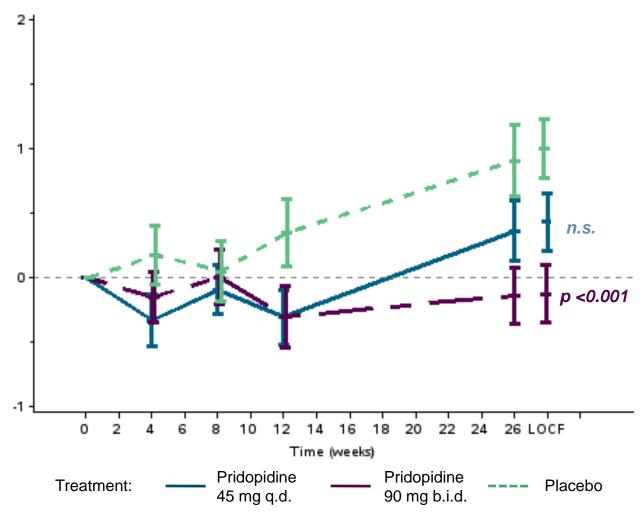












Efficacy results consistent accros ITT and PP



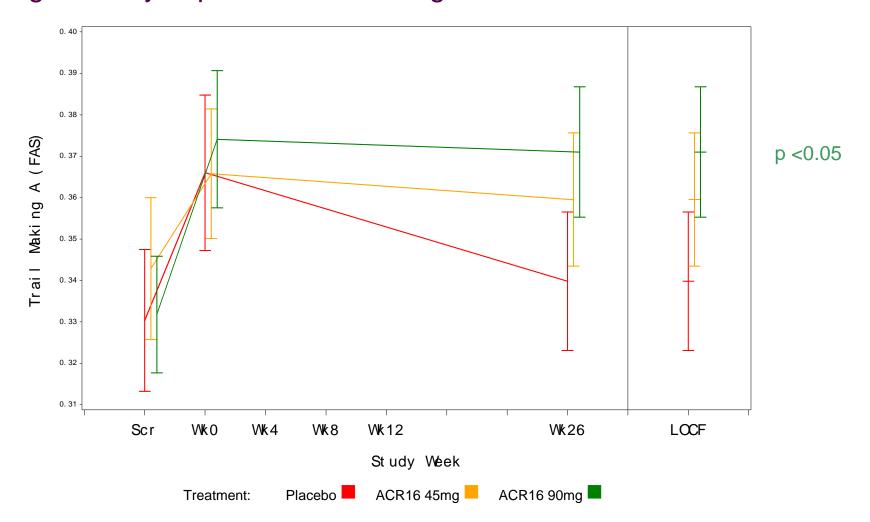
- ➤ ITT population = 437 randomised HD patients
- ➤ PP population = 357 patients, who completed the study according to the protocol or with minor protocol violations

Motor scale	Significance level for the ITT population	Significance level for the PP population
Modified Motor Score, mMS	p <0.02	<i>p</i> <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



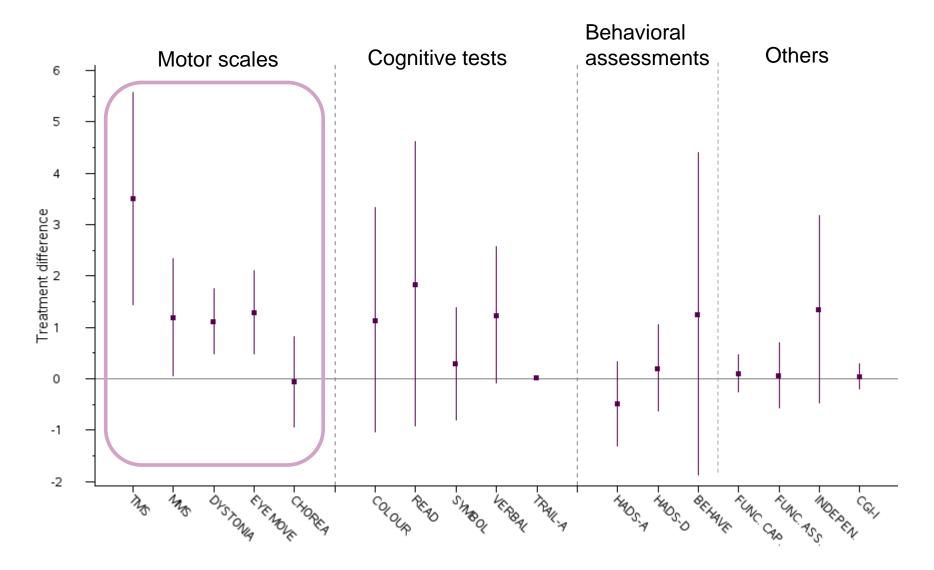


Significantly improved trail making









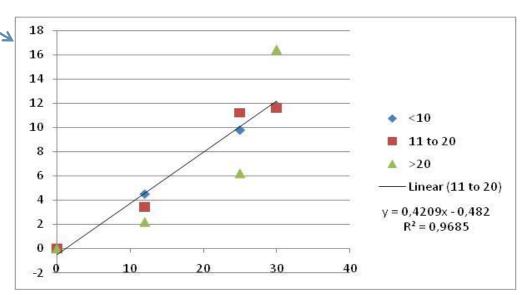
The MermaiHD study results; Clinical relevance of treatment effect



➤ 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







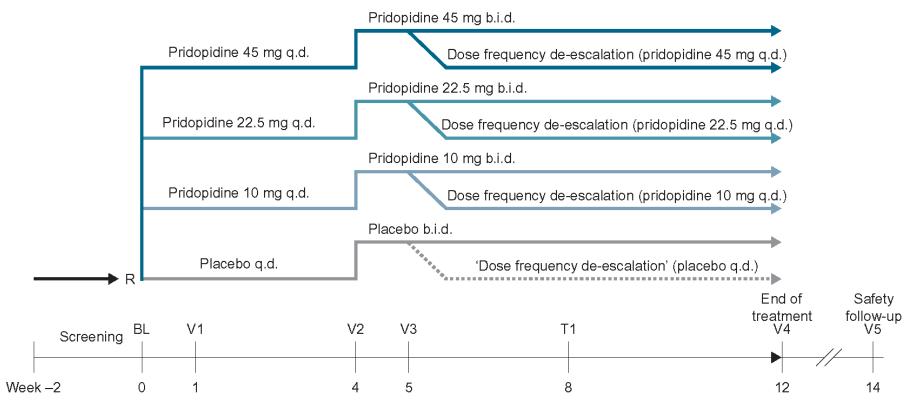
In the MermaiHD study, Huntexil® has demonstrated to

- 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® - 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 initiated after 6 months MermaiHD results

Other initiatives

- Cost-of-illness study ongoing in major markets to support the overall benefit of Huntexil®
- Named Patient Programme potential launch in Europe in H1 2010
- Clinical publication strategy



For more information, please visit www.neurosearch.com or write to investor@neurosearch.dk

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