

FAIR PARK II Clinical Trial - Newsletter n°35



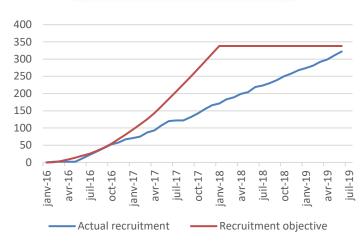
Main Figures

- 24 initiated study centers (100 %)
- 322 patients randomized (92 %)
- 5 patients pre-screened
- **32** screen-failures (9%) : be careful not to enroll too severe patients
- **72** drop-outs (22,3%): it is very important to limit drop-outs by educating the patients

Database quality check

- The sponsor envisions to recruit 33 more patients, to allow a sufficient statistical power in the analysis. A request is under review by all partners to ask for an extension of 12 months (6 months to complete the recruitment) to the European Commission.
- → Please avoid missing data for the primary criterion (MDS-UPDRS) on the randomization visit, week 36 and week 40 visits.
- → In order to avoid inconsistent data, MDS-UPDRS must be performed by the same investigator, in the same conditions for each patient.

Recruitment Progress



	COMPETITIVE RECRUITMENT									•			_				-								
										6							(4)								
•	• nspark FCRIN NETWOOK	Lille	Paris	Clermont Ferrand	Lyon	Toulouse	Strasbourg	Marseille	Bordeaux	Hospital Clinic Barcelona	Germans trias & Pujol Hospital	San Pau Hospital	Medical University Innsbruck	Charles University Prague	Newccastle University	London	University Hospital Cambridge	CH Lisboa Norte	CH Alto Ave	CH de Coimbra	Christian Universitat zu Kiel	Homburg	Rostock	Radboudumc Nijmegen	Academic Medical Center Amsterdam
	Initiation visit	01 Feb 16	17 Mar 16	10 Mar 16	24 Apr 16	15 Mar 16	03 Mar 16	19 Apr 16	09 May 16	30 Aug 16	20 Apr 17	15 Mar 17	17 Oct 16	06 Sep 16	16 Aug 16	3 July 18	11 May 17	07 Sep 17	3 Apr 17	11 May 17	9 Nov 16	27 Oct 16	29 Nov 16	31 Aug 16	12 Jan 17
	N° inclusions	5 1 ↑	20	8	22	14	26	18↑	16	15↑	13	8	5	12	9↑		3↑	2	16	10	14	2	10	17	11↑
	Drop-outs	3 6%	5 25%	5 63%	4 18%	4 29%	8 31%	7 39%	3 19%	2 13%	1 8%	1 13%	0 0%	2 17%	2 22%		0 0%	0 0%	1 6%	1 10%	7 50%	1 50%	3	10 ↑ 59%	2 18%

Sponsor: CHRU de Lille, 2 avenue Oscar Lambret, 59037 LILLE Cedex, FRANCE

www.fairpark2.eu

