Supplementary File 1 - World Health Organization Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov Identifier: NCT02495181
Date of registration in primary registry	March 23, 2015
Secondary identifying numbers	EudraCT number: 2015-001368-20
Source(s) of monetary or material support	This study was supported by Bayer HealthCare Pharmaceuticals Inc.; Bayer Portugal, SA
Primary sponsor	AIBILI – Association for Innovation and Biomedical Research on Light and Image
Secondary sponsor(s)	NA
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Public title	PROTOCOL FOR A RANDOMISED, DOUBLE-MASKED, SHAM-CONTROLLED PHASE IV STUDY ON THE EFFICACY, SAFETY AND TOLERABILITY OF INTRAVITREAL AFLIBERCEPT MONOTHERAPY COMPARED TO AFLIBERCEPT WITH ADJUNCTIVE PHOTODYNAMIC THERAPY IN POLYPOIDAL CHOROIDAL VASCULOPATHY – THE ATLANTIC STUDY
Scientific title	The ATLANTIC Study
Countries of recruitment	Portugal and Spain
Health condition(s) or problem(s) studied	Polypoidal Choroidal Vasculopathy
Intervention(s)	Sham Comparator: Aflibercept + Verteporfin PDT - IVT Aflibercept 2 mg on a Treat & Extend Regimen + Verteporfin PDT
	Sham Comparator: Aflibercept + Sham PDT IVT Aflibercept 2 mg on a Treat & Extend Regimen + Sham PDT
Key inclusion and exclusion criteria	Inclusion Criteria: 1. Age ≥ 50 2. Either gender

	3. Treatment-naive PCV patients 4. BCVA at study entry from 25 to 80 ETDRS letters (Snellen Equivalent 20/320 to 20/25) 5. Presence of PCV in the study eye assessed by the Central Reading Centre based on multimodal retinal imaging (CFP, SD-OCT, FA and ICGA), including the presence of active polyps on ICGA, with or without branching vascular network. Subfoveal involvement is required, with intraretinal or subretinal fluid and/or subfoveal PED seen on SD-OCT. 6. Greatest linear dimension of the lesion of ≤ 5400 µm, assessed by FA/ICGA angiography. 7. Women must be post-menopausal for at least 12 months prior to trial entry, or surgically sterile, or in case of child-bearing potential, women must be using highly effective method of birth control (i.e. one that results in a failure rate less than 1% per year when used consistently and correctly, such as, combined hormonal contraception, progestogen-only hormonal contraception, intrauterine devices (IUD), intrauterine hormone-releasing system (IUS), bilateral tubal occlusion, vasectomized partner, and sexual abstinence). 8. Ability to provide written informed consent. 9. Ability to return for all study visits.

	Exclusion criteria: 1. Active ocular or periocular infection or inflammation in the study eye. 2. Uncontrolled intraocular pressure in the study eye. 3. Ocular condition in the study eye likely to impact vision and confound study outcomes (e.g. vitreomacular traction, epiretinal membrane with severe retinal folds, ocular inflammation, retinal vascular diseases like diabetic retinopathy or diabetic macular edema). 4. Presence of centromacular scarring or atrophy indicating irreversible BCVA loss. 5. Prior treatment of the study eye with any anti-VEGF agents 6. Systemic use of anti-VEGF products within 3 months prior to the study entry. 7. Previous intraocular surgery, macular laser treatment, PDT, or intraocular steroids in the study eye. 8. Known serious allergies or history of hypersensitivity to fluorescein, indocyanine green, verteporfin or components used on Eylea® formulation. 9. Subject with a condition (such as advanced, severe or unstable disease or its treatment) or subject in a situation which may put him/her at significant risk, confound the study results or significantly interfere with the subject's participation in the study. 10. History of porphyria and clinically relevant impairment of liver function.
Study type	Interventional
	Allocation: randomized intervention model. Parallel assignment masking: double blind (subject, investigator, data entry person, technicians)
	The purpose of this study is to compare the efficacy and safety of intravitreal Aflibercept (IVA) with sham PDT (sPDT) versus IVA with verteporfin PDT (vPDT) in a Caucasian population with treatment-naive PCV, enrolling into a treat and extend (T&E) regimen
	Phase IV
Date of first enrolment	FPFV: January 2016
Target sample size	50
Recruitment status	Recruiting