Patient Education to improve Immune Checkpoint Inhibitor tolerance: EDHITO a multicentre randomized controlled trial

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BACKGROUND

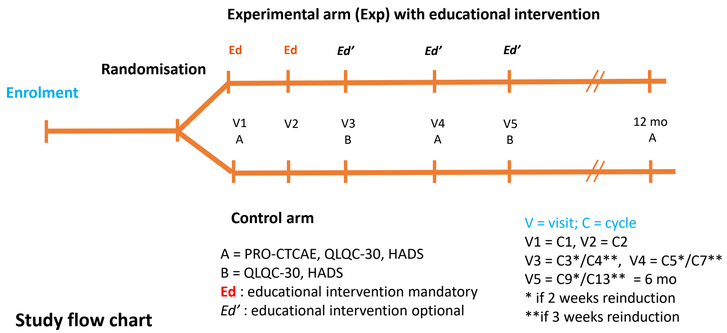
Immune Checkpoint Inhibitor (ICI) improve overall survival in patients with poor prognosis cancer. However, ICI induce immune-related adverse Events (irAEs) that impair patient's Quality of life. Empowering patients through education could lead to better management of toxicities.

We conducted a clinical trial to highlight the impact of Patient Education: EDHITO NCT03948724.

METHODS

A multicentre randomized (2:1) controlled trial was conducted to compare the effect of educational sessions (experimental arm) to a control group (standard of care). The main objective was to compare irAEs Gr≥3 (CTCAEv5,0) in both group of patients. Patients naive of ICI, regardless of location, stage of disease, or treatment association were eligible.
Identical educational sessions for patients in experimental arm were provided, in every participating hospital.

A partnership with Gustave Roussy's Pharmacovigilance Unit (GRPU) has made it possible to validate all irAEs and feed the REISAMIC database.



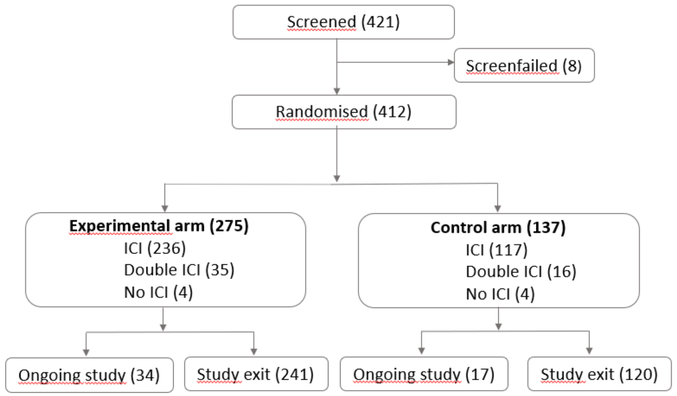
Study flow chart

RESULTS

From december 2019 to Auguste 2024, 412 pts were randomised: 275 pts Exp Arm; 137 control arm.

Gender-ratio M/F (N(%)) 275(67)/137(33), median age 67 [30-91], Age distribution : 18-64 : 170(41), 65-85 : 235(57), >85 : 7(2). Preexisting autoimmune disease 15(4)

404(98) pts received ICI, 51 a dual ICI, 137(36) ICI associated with chemotherapy or TKI, 64(17) associated with radiotherapy.



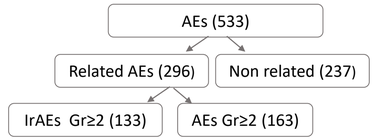
Enrolment flow chart (N)

Centre	N
Institut Bergonié, Bordeaux	4
Pôle cancérologie, CHU St Etienne	4
Centre Eugène Marquis	5
Centre Léon Bérard, Lyon	6
Institut Curie, Paris	8
CH Emile Roux, Le Puy en Velay	9
CH St Malo, St Malo	9
ICL, Vandoeuvre-lès- Nancy	10
Dermatologie, CHU Angers	11
CHD Vendée, La Roche/Yon	20
Urologie, CHU Angers	25
Oscar Lambret, Lille	54
ICO, St Herblain	118
ICO, Angers	129
Total	**412**

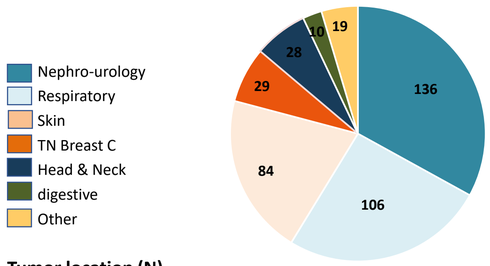
Randomization / centre (N)

ICI	N
Pembrolizumab	186
Nivolumab (of wich 49 + ipilimumab 1 + pembrolizumab)	158
Avelumab	26
Durvalumab (of wich 1 + tremelimumab)	21
Atezolizumab	9
Cemiplimab	3
Dostarlimab	1
No ICI	8

Distribution ICI (N)



Imputability of irAEs according to GRPU (N)



Tumor location (N)

Educational intervention	Exp (275)	Control (137)
1st visit	266 (97)	1 (1)
C1	263 (96)	1 (1)
C2	234 (85)	0
6 mo	87 (32)	0

Individual educational intervention N(%)

CONCLUSIONS

This ongoing trial, with the last follow-up due to August 2024, will assess the effect of education on patient with ICI. Increasingly widespread use of ICI (in early stage, with new indications eg. TNBC, new combinations, occurrence of irAEs after discontinuation of treatment) makes patient education and empowerment essential for an early detection and management of toxicities.

As monitoring is still in progress, only descriptive data are available.

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