

## Summary of Main Trial Results for the De-ESCALaTE HPV Study

Written by Patients for Patients

**Background:** The incidence of human papillomavirus (HPV)-positive oropharyngeal cancer is rapidly increasing and is affecting younger patients. Cetuximab was believed to have less side-effects than the standard treatment with cisplatin, but this had not been tested in a clinical trial.

**Methods:** De-ESCALaTE HPV was a randomised trial carried out at 32 head and neck treatment centres in Ireland, the Netherlands, and the UK. Eligible patients were aged 18 years or older, with HPV-positive low-risk oropharyngeal cancer. The patients were randomly assigned to receive, in addition to radiotherapy, either cisplatin (standard treatment) or cetuximab. The primary outcome was overall severe toxicity events at 24 months from the end of treatment. Secondary outcomes included overall survival and recurrence.

**Findings:** 334 patients were recruited between November 2012 and October 2016. The table shows the results for each treatment, cisplatin or cetuximab:

	TREATMENT		COMMENT
	CISPLATIN (standard care)	CETUXIMAB	
Number of patients	166	168	
Severe Toxicity (mean number of events)	4.8	4.8	No significant difference
2 year overall survival rate	97.5%	89.4%	Cisplatin significantly better
2 year recurrence rate	6%	16.1%	Cisplatin significantly better

**Interpretation:** Cisplatin and radiotherapy should remain the standard of care for HPV-positive low-risk patients who are able to tolerate cisplatin.

**Funding:** Cancer Research UK.

This trial is registered with the ISRCTN registry, number ISRCTN33522080.

The results from the De-ESCALaTE HPV study have been published online in *The Lancet*:

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(18\)32752-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)32752-1/fulltext)

**Note:** We acknowledge the work of Malcolm Babb (President of The National Association of Laryngectomee Clubs and independent Trial Steering Committee patient representative) and Ralph Goodson (Communications Officer, Heads2gether, The National Head & Neck Cancer Support Group and independent Trial Steering Committee patient representative) in producing this summary.

Malcolm Babb said, "From a patient perspective, De-ESCALaTE has been a success by providing definitive information about the comparative effectiveness of treatment choices."

Ralph Goodson said, "It is only through research like this that effective treatments can be honed."