Table 1: Controlled clinical trials of lycopene for cancer

Source: Ava Lorenc, CAM-Cancer Consortium. Lycopene [online document]. http://cam-cancer.org/en/lycopene, November 2020.

First author, year	Study design	Participants (number, diagnosis)	Interventions (experimental treatments, control)	Main outcome measures	Main results	Comments
Treatment						
Paur 2016	RCT	Men with prostate cancer (n=79)	1) Tomato products (30mg lycopene/day) 2) Tomato products plus other supplements 3) Standard care	1) PSA 2) Plasma carotenoids 3) Fatty acids in red blood cells 4) Selenium	No significant differences between groups for total sample. In a subgroups of intermediate risk prostate cancer patients PSA was significantly decreased in the tomato product only group compared to control (p=0.016). Plasma lycopene was significantly higher in groups 1 and 2. Selenium and fatty acids only changed in group 2.	High-quality study with a powered sample size, although patients could not be blinded. Self-reported compliance was 99% in group 1 and 96-99% in group 2.
Prevention						
Beynon 2018	RCT	Men at risk of prostate cancer (raised PSA levels) (n=128)	1) Lycopene supplements 2)Lycopene-rich diet 3) Placebo lycopene supplements 4) Green tea supplements 5) Green tea drink 6) Placebo green tea supplements	159 metabolic traits e.g. amino acids, glycolysis measures, ketone bodies and inflammatory markers	Metabolites altered in response to lycopene supplement were acetate (p=0.003), pyruvate (p=0.006) valine (p=0.004) and docosahexaenoic acid (p=0.006). In lycopene diet group valine (p=0.001) and diacylglycerol (p=0.006) were lower. Observational data suggest pyruvate may boost prostate cancer risk.	High adherence to intervention. Study was not powered (designed as a feasibility study).

Oral submucous fibrosis (OSMF)						
Beenakumary 2019	RCT	Patients with oral submucous fibrosis (OSMF) (n=60)	1) Lycopene supplement 2) Lycopene supplement + dexamethasone 3) Dexamethasone + hyaluronidase	1) Burning sensation (VAS) 2) Mouth opening 3) Patient satisfaction	Significant decrease in burning sensation in group 3 compared to 1 and 2 at 2nd month (p=0.021) but not 3rd month. Significant improvement in mouth opening in group 3 compared to 1 and 2 at 3rd month (p=0.025).	With no standard care control group it is difficult to evaluate the effects of lycopene. Study was not powered
Saran 2018	RCT	Patients with oral submucous fibrosis (OSMF) (n=60)	1) Lycopene (4mg) 2) Curcumin (300mg) 3x/day for 3 months	1) Mouth opening 2) Burning sensation (VAS)	No difference in burning sensation. Lycopene resulted in better improvement in mouth opening ($p<0.05$)	Study was not powered. With no standard care control group it is difficult to evaluate the effects of lycopene.
Karemore 2012	RCT	Patients with oral submucous fibrosis (OSMF) (n=92)	1) Lycopene supplement (4mg 2x/day) 2) Placebo supplement	1) Mouth opening 2) Examination (looking for erythematous areas, ulceration, erosions) 3) Burning sensation	Lycopene significantly improved mouth opening ($p<0.05$) and burning sensation ($p<0.05$). No significant change in examination outcomes.	Very poorly written with many details missing. Not powered. No details of randomisation method.
Nephrotoxic side effects of cancer treatment						
Mahmoodnia 2017	RCT	Patients with cancer (candidates for cisplatin-based chemotherapies (n=120)	1) 25mg lycopene during the period 24 hours before to 72 hours after cisplatin administration 2) Standard care	1) Blood urea nitrogen (BUN) 2) Serum Cr 3) Glomerular filtration rate (GFR)	No significant changes in Cr levels. GFR increased in the lycopene group and then decreased partially with significant time and group interaction (p=0.004). BUN decreased but then increased, with significant time and group interaction ($p<0.001$).	The study was double-blind and adequately randomised but lacks information on the sample and follow up. The outcomes may not allow for early detection of nephrotoxicity.