

# He'll even bring her the moon to make her live...

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Kusum, a non-smoker, at the age of 29, was diagnosed with stage IV lung cancer metastatic to brain. In 2014, her disease got resistant to all available applicable medicines in India (though they were available in western countries via approval or clinical trials). She almost lost her life to this wretched disease due to unavailability of any medicine. To get any cancer medicine approved in India, it should go for clinical trials, whether it is already approved in other countries. In India, there are

or not. In

Kusum Malik Tomar

only 1.4% of global trials going on, which leads to almost no access of the latest medicines/ treatment options for Indian citizens. Fortunately, after 3 months of battle of survival, Kusum came across a new clinical trial in India and decided to participate.

The story of Kusum's fight starts around 5 years back. Kusum hails from Gurgaon, close to Delhi and was having a peaceful life with her loving family consisting of Vivek, her husband, and their son. One day, while on a shopping spree, Kusum felt a weird twitching in her face. As she was a migraine patient, they thought of consulting a neurologist who in turn suggested an MRI scan. The results came up showcasing six nodules at the right side of her brain.

Vivek and Kusum were shattered literally. A pharmacist by qualification and a pharmaceutical regulatory professional, Vivek from Shamli, UP, met Kusum from a small town Rohtak, Haryana, during her stint as a researcher at a pharmaceutical company in Ahmedabad, Gujarat. They were married in 2007 and blessed with a baby boy in 2009. Hailing from a middle class family, he left his family as he was posted in Hyderabad by his firm. After 4 years, he had just been reunited with his family and life had been running smooth until this life-shattering incident happened.

Treatments followed suit. After 5 months, they took another MRI and to their utter dismay, found out that those six nodules have increased to an alarming ten. To correct their wrong diagnosis, Kusum was directed to an oncologist without delay. Till then, Vivek and Kusum hadn't revealed anything about her disease to their parents. In September 2012, after the biopsy which confirmed

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**Kusum Malik Tomar and Vivek Tomar with their son.**

lung cancer-metastatic to brain at stage IV, Vivek and Kusum shared the details of the disease with their parents.

Doctors advised Kusum to have brain radiation. She underwent whole brain radiation followed by 3 cycles of chemotherapy. “We went for innovative products instead of generic medicine because we wanted to try our best and leave no stone unturned. We chose Alimta along Cisplatin, a harsh but powerful drug against lung cancer. She stood very strong during the treatment,” says Vivek who was the staunch pillar of support for Kusum.

But after a few days, she started having complaints of shoulder pain and this was worrisome. After a 2D Echo Test, she was directly taken to operation theatre as her condition had become critical. She had a severe level of pericardial fluid accumulated in the pericardial cavities which might block the blood pumping to her heart at any time. By then, Kusum had become unconscious and while in the ICU, doctors removed around 1.925 L of cancerous fluid in two days from around the heart and lungs. The fluid was tested and they confirmed that the medicine had no effect on the disease.

Further testing suggested that Kusum has a rare type of cancer mutation that is ALK mutation of NSCLC. From the doctors, Vivek and Kusum came to know about a medicine from Pfizer called *Crizotinib*, which recently got approved as molecular therapy for ALK mutation. “We decided to give it a



try. We brought the medicine from Germany. During that time, clinical trials were not mandatory for medicines like that. From December 2012 to September 2014, the period we used that medicine, with a good quality of life. There were some side effects but mostly negligible,” Kusum recollects.

In Sept 2014, they came to know that the new medicine also failed. It has begun to grow resistance. “But it was quite normal with Stage IV disease. At some point of time, the disease grows resistance against the medicine. We needed a better medicine. We began the search and found that a next level drug from *Novartis* named *Zykadia (Ceritinib)* approved and available in US,” adds Vivek.

By then, laws had been changed after the Supreme Court directed the health ministry to bring clear guidelines for clinical trials. Some NGO had submitted a Public Interest Litigation (PIL) on the number of deaths occurred during clinical trials. The government has made it mandatory to have clinical trials for new medicines and the laws were so difficult that only a few medical companies, doctors and research institutions went on for clinical trials in India. For months Vivek did everything to contact and get latest medicine for Kusum for whom there is lack of time. “My routine work those days was to take laptop to the hospital and to contact and pursue number of doctors, hospitals and medical companies for clinical trials of new medicines in India but nothing worked out,” Vivek looks back at those difficult moments.

In November 2014, Delhi hosted the SAARC Countries On-

cology meet. Vivek came to know about it. He and Kusum attended the meet and during the question-answer session, Kusum got a chance to share her heart-wrenching plight. She was almost on the verge of tears as she concluded asking what her fault was for not allowing to get the needed medicine to sustain her life. For a moment, pin drop silence prevailed at the venue. But Kusum’s voice reached to right stakeholders. When one door closes, another surely opens. The couple found another solution to their problem. Novartis Company representatives who were present for the conference took the topic and the company pushed their medicine for clinical trials in India for Kusum.

Finally in December, the clinical trial was approved. Rajeev Gandhi Cancer Institute and Research Centre, New Delhi was the only hospital approved for clinical trial. Since the calcium level of Kusum was not matching as per the protocol of trial, two times they had to return. Finally on January 1st, 2015, she became the first patient of clinical trial for this medicine. She was just going to lose her life before that clinical trial saved her life.

Since two years, Kusum is part of this clinical trial. And it is because of Kusum and other patients participated in clinical trial, Ceritinib is now approved in India and available at a very economical rate compared to western countries. However; now Kusum is again in requirement of next level medicine as the current drug started to get resistance in brain. There are around 18 next level treatment options available either as approved or via clinical trials for ALK +ve patients in other countries but in India, there is nothing.

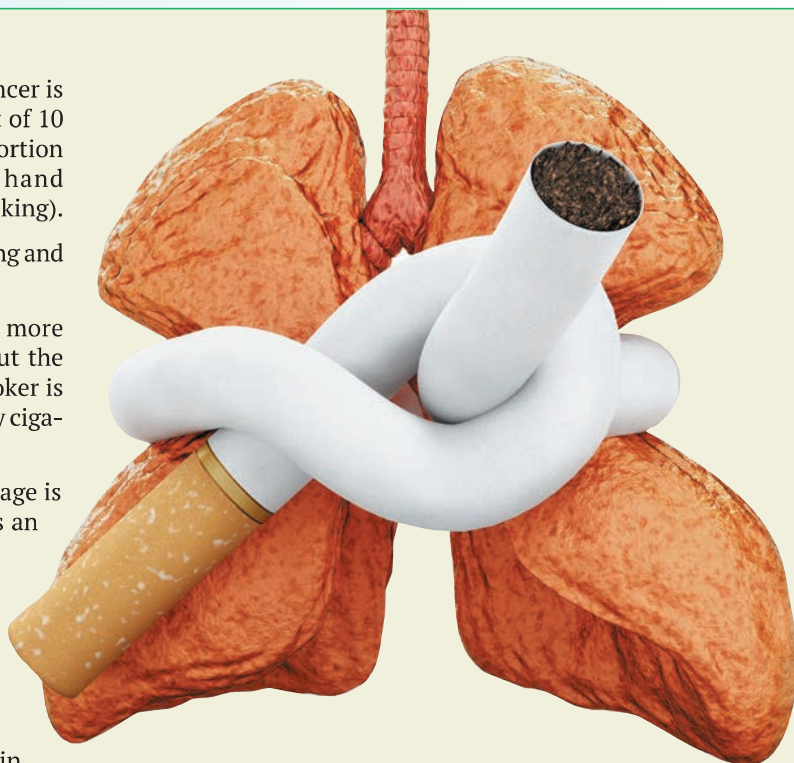
Meanwhile Kusum’s condition grew more difficult as four

**Smoking and lung cancer**

By far the biggest cause of lung cancer is smoking. It causes more than 8 out of 10 cases (86%) including a small proportion caused by exposure to second hand smoke in non smokers (passive smoking).

Here are some facts about smoking and lung cancer.

1. The more you smoke, the more likely you are to get lung cancer but the length of time you have been a smoker is even more important than how many cigarettes you smoke a day
2. Starting smoking at a young age is even more harmful than starting as an adult
3. Stopping smoking reduces your risk of lung cancer compared to continuing to smoke. The sooner you quit, the better your health - but it’s never too late
4. Passive smoking (breathing in



**Kusum Malik Tomar and Vivek Tomar with their son.** (File Picture)



months ago, she began to develop seizures.

## Clinical trials in India

Kusum's condition made Vivek an activist now. After experiencing how clinical trial proved vital in her life and the struggle associated to get access to latest medicines and clinical trial, Kusum and Vivek have started to work actively with patients, NGOs, industry organizations, regulators at FDA/ government and doctors on clinical trial awareness and raising support to change the current clinical trial situation in India so that no Indian patient should die due to unavailability of medicine that is available somewhere in world. "

"Clinical trials is the only way to get the latest, better and safest medicine. Not only western countries but many Asian countries like Malaysia, South Korea and Singapore are 10 years ahead of us in clinical trials. Actually, why do we need clinical trials for drugs that are approved by other countries? We should try to avoid the delay," Vivek points out.

other people's cigarette smoke) increases the risk of lung cancer, but it is still much less than if you smoke yourself

It is almost impossible to work out the risk of occasional passive smoking.

We know that the risk of lung cancer for passive smokers goes up the more cigarette smoke they are exposed to. Overall, people exposed to environmental tobacco smoke at work or at home have their risk of lung cancer increased by about a quarter compared to people who are not exposed to it. Heavy exposure to environmental tobacco smoke at work has been shown to double the risk of lung cancer.

Cigarette smoking is the main cause of lung cancer. But pipe and cigar smokers are still much more likely to get lung cancer than non-smokers. They are also much more likely to get cancer of the mouth or lip.

In the past, lung cancer has been more common in men than women. Now, because more women smoke, it is almost as common in women.

However long you have been smoking, it is always worth giving it up. ■

He puts up his case with Oncology." In India every treatment starts with Chemo therapy for Oncology. The third state is mostly radiation. Butmolecular therapy is notused as first linetreatment. But in many countries, especially western countries,treatment start with molecular therapy. The new method they are working now is molecular therapy andimmunotherapy combination. You know the side effects of chemo therapy- irrespective of good or bad cells, it destroys everything. In molecular therapy, only bad cells are destroyed and immunotherapy, they help the good cells to destroy the bad cells," Vivek makes his point with the thorough knowledge in this realm.

He invites the attention to a case of a patient at Chennai whom he met during his search for clinical trials in India. Unfortunately, the patient died last week because all approved medicines in India failed. "He was just 29 years old. In his case, there was a medicine already approved in US, Canada and Japan. It was available by approval/ trial in Singapore, Thailand, Taiwan and whole Europe, but not in India. We believe that every Indian's life is important," comments the activist inside Vivek.

Vivek and Kusum today are strong advocates of approving clinical trials in India. He actively takes part in discussions in social media and works with several NGO's in promoting clinical trials. For him, you should never give up hope. "Fight is the best hope. I will not leave any stone unturned for my love, my wife. I will try every possible extend to save her from the clutches of this wicked disease," Vivek is brimming with confidence and optimism. ■